## APPENDIX A

**United States Court of Appeals**
**For the First Circuit**

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No. 08-1409

UNITED STATES, ex rel. Mark Eugene Duxbury and Dean McClellan,

Plaintiffs,

MARK EUGENE DUXBURY; DEAN MCCLELLAN,

Plaintiffs, Appellants,

v.

ORTHO BIOTECH PRODUCTS, L.P.,

Defendant, Appellee.

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APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Rya W. Zobel, U.S. District Judge]

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Before

Torruella, Circuit Judge,
Siler,* Senior Circuit Judge,
and Howard, Circuit Judge.

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* Of the Sixth Circuit, sitting by designation.

Jan R. Schlichtmann, with whom Paul Simmerly, Heman Recor Araki Kaufman Simmerly & Jackson, PLLC, Robert Foote, Mark Bulgarelli, Foote Meyers Mielke & Flowers, LLC, Kathleen Chavez, and Chavez Law Firm, PC, was on brief for appellants.

Ethan M. Posner, with whom Patrick S. Davies, Jennifer L. Saulino, Andrew W. Lamb, Covington & Burling LLP, Susan L. Burke, and Burke O'Neil LLC, was on brief for appellee.

Jamie Ann Yavelberg, with whom Charles W. Scarborough, Douglas N. Letter, Attorneys, Appellate Staff, Civil Division, Gregory G. Katsas, Assistant Attorney General, and Michael J. Sullivan, United States Attorney, was on brief as amicus curiae for the United States.

Cleveland Lawrence III, on brief as amicus curiae of Taxpayers Against Fraud Education Fund in support of appellants.

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August 12, 2009

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**TORRUELLA, Circuit Judge.** This appeal concerns the qui tam provisions of the False Claims Act (the "FCA"), 31 U.S.C. § 3730, which allow whistleblowers (called "relators") to bring certain fraud claims on behalf of the United States.[1] The relators in this case, the plaintiffs-appellants Mark Duxbury and Dean McClellan (together, the "Relators"), alleged that defendant-appellee Ortho Biotech Products, L.P. ("OBP") violated the FCA in unlawfully promoting the sale of its drug Procrit. The district court dismissed all of the Relators' claims, and this appeal followed. After careful consideration, we affirm in part and reverse in part.

## I. Background

### A. The FCA

To provide context, we start with the statutory scheme. The FCA contains qui tam provisions that "supplement federal law enforcement resources by encouraging private citizens to uncover fraud on the government." Rost, 507 F.3d at 727. The qui tam

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[1] As we have previously noted:

> "Qui tam" comes from the phrase "qui tam pro domino rege quam pro se ipso in hac parte sequitur," which translates as "who pursues this action on our Lord the King's behalf as well as his own."

United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 n.4 (1st Cir. 2007) (quoting Rockwell Int'l Corp. v. United States, 549 U.S. 457, 463 n.2 (2007)), overruled on other grounds by Allison Engine v. United States ex rel. Sanders, 128 S. Ct. 2123 (2008).

provisions permit whistleblowers (known as relators) to bring certain fraud claims on behalf of the United States; in return, "[a] private relator is entitled to a portion of any proceeds from the suit, whether the United States intervenes as an active participant in the action or not." Id. at 727.

"The qui tam mechanism has historically been susceptible to abuse, however, by 'parasitic' relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise uncover." Id. Accordingly, Congress has amended the FCA several times "to walk a fine line between encouraging whistle-blowing and discouraging opportunistic behavior." See United States ex rel. S. Prawer v. Fleet Bank of Me., 24 F.3d 320, 324-26 (1st Cir. 1994) (quoting United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 651 (D.C. Cir. 1994) (detailing the history of such amendments to the FCA's qui tam provisions)).

As a result of these amendments, the FCA includes jurisdictional bars that limit a district court's subject matter jurisdiction over qui tam actions. Two of these bars are relevant to this action. The first, known as the "public disclosure" bar, provides that a court does not have subject matter jurisdiction over any qui tam action that is "based upon the public disclosure of allegations or transactions" concerning the alleged fraud, unless, among other things, "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A). A relator qualifies as an "original source" if (1) she has "direct and independent knowledge" of the information supporting her claims and (2) she "provided the information to the Government before filing an action." Id.

§ 3730(e)(4)(B). The second, known as the "first-to-file" bar, provides that when a potential relator brings an FCA action, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." Id. § 3730(b)(5).

**B. The Complaints**

OBP distributes and promotes Procrit -- the brand name for epoetin alfa -- a drug approved by the FDA for use to treat anemia resulting from chemotherapy, chronic kidney disease, HIV infection, and blood loss from certain types of surgery. Both Relators were sales representatives for OBP who were responsible for the promotion and sale of Procrit in the Western United States. From 1992 to 1998, OBP employed Relator Duxbury, first as a Product Specialist and later as a Regional Key Account Specialist for OBP's Western Division Oncology sales force. From 1992 to 2004, OBP employed Relator McClellan, also first as a Product Specialist but later as a Territory Manager for OBP's Western Division Oncology sales force.

This appeal turns on a number of complaints filed by the Relators and other parties, which we discuss in some detail below.

On November 6, 2003, Duxbury, but not McClellan, filed a complaint (the "Original Complaint") in the District Court for the District of Massachusetts. The Original Complaint contained allegations concerning OBP's fraudulent reporting of the Average Wholesale Price ("AWP") of Procrit, a benchmark used by the Medicare program for reimbursement purposes. It was filed hot on the

heels of a master consolidated complaint (the "MCC") filed in September 2002 in a multi-district litigation concerning the fraudulent reporting of AWP. See generally In re Pharm. Indus. Average Wholesale Price Litig., MDL No. 1456, No. 01-12257-PBS (the "AWP MDL").[2]

The Original Complaint contained two counts, one alleging "substantive violations" of the FCA and the other a conspiracy count. (Compl. ¶¶ 47-55 (Count I); id. ¶¶ 56-60 (Count II)). In support of the counts, the Original Complaint alleged that OBP published a fraudulently inflated AWP for Procrit, which resulted in the filing of false claims for reimbursement with the Medicare program. (Id. ¶¶ 1, 29). The Original Complaint further alleged that OBP marketed the "spread" -- the difference between the higher, fraudulent AWP and the lower, actual cost of Procrit -- to induce medical providers to purchase Procrit. (Id. ¶¶ 23, 29). Thus, according to the Original Complaint, the "spread" not only caused the filing of false claims, but constituted an "illegal kickback" to health care providers. (Id. ¶¶ 23, 30).

The Original Complaint also alleged that OBP provided "free samples" of Procrit as well as "non-public financial inducements," such as rebates, discounts, "unrestricted education grants," and "phony drug studies." (Id. ¶¶ 31, 34, 38, 40, 43).

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[2] For background concerning the AWP MDL, which is quite complex, see In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20 (D. Mass. 2007).

OBP allegedly used these inducements "to lower the providers' net cost of purchasing Procrit," and further "inflate[] the AWP," as "the value of these services was kept off the book, so as not [to] be reflected in the AWP." (Id. ¶ 34; see also id. ¶¶ 32-33). The Original Complaint alleged that these inducements also constituted illegal kickbacks. (See id. ¶¶ 3, 45).

With respect to the "phony drug studies," the Original Complaint alleged at Paragraphs 40 through 42 that OBP utilized "Phase IV Marketing Trials" to, among other things, "encourage the physician, clinic, or hospital to use the drug in a way which [wa]s inconsistent with its FDA approved indications and administration methods." (Id. ¶ 40(c)). The Original Complaint referred specifically to a 1997 trial in which OBP allegedly

> paid physicians to dose Procrit at 40,000iu in a once per week dose instead of the FDA approved dosage of 10,000iu three times per week dosage in cancer-chemotherapy patients. The trial was very successful and the once per week dosage is now universally accepted among oncologists. The trial's success also resulted in Medicare Part B paying for 40,000iu/week of Procrit in cancer chemotherapy patients instead of 30,000iu/week -- an increase in 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia.

(Id.) (emphasis in original). The Original Complaint further alleged that "[t]he 40,000iu dosage scheme was successful for Ortho and doctors, but Ortho ha[d]

not received FDA approval for such dosage." (Id. ¶ 41) (emphasis in original).

On December 19, 2003, about one month after the filing of the Original Complaint, Kurt Blair, also a former OBP sales representative, filed a qui tam complaint (the "Blair Complaint") against OBP in the District Court for the District of Colorado. The Blair Complaint contained two counts. Count I alleged that, beginning in 1998, OBP promoted "a dosing regimen of 40,000 units once per week" even though it had not received approval from the FDA for such a high dosage. (Blair Compl. ¶¶ 22-27). Blair claimed that OBP promoted this unapproved, "off-label" dosage through a variety of means, such as direct off-label marketing to medical professionals; influencing the results of purportedly independent clinical studies; and rebate programs offered to induce increased prescriptions of Procrit, among other things. (Id. ¶¶ 27, 28-79). Blair alleged that OBP's promotion of this off-label use caused the filing of "false" claims for reimbursement with Medicare and Medicaid, insofar as the providers sought reimbursement for "nonreimburseable" uses. (Id. ¶¶ 88-91). Count II alleged that OBP caused the submission of false claims by, among other things, "paying thousands of kickbacks to Medicaid and Medicare providers, causing the providers to write tens of thousands of prescriptions for Procrit that would otherwise not have been written." (Id. ¶ 93).

As required under the FCA, both the Original Complaint and the Blair Complaint were filed under seal to allow the United States time to review both

complaints and decide whether to intervene. 31 U.S.C. § 3730(b)(2).[3] On March 23, 2004, the Blair district court allowed the government's motion to partially lift the seal on the Blair Complaint in order to disclose it to Duxbury.

On July 18, 2004, Duxbury, through his counsel, provided a written disclosure of information (the "Information") to the Department of Justice (the "DOJ"). The Information was sent in response to a April 6, 2004 letter by the DOJ summarizing the allegations in the Original Complaint and requesting further information. The Information stated that "[w]e believe the following paragraph describes a more important and damaging fraud identified in Mr. Duxbury's complaint, which we described (see Complaint ¶¶ 40-42) but are not sure you have grasped based on your letter and the interview of Mr. Duxbury." The "following paragraph" stated in part:

> In 1997, [OBP] initiated an intentional scheme to promote an illegal, off-label dosage of

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[3] 31 U.S.C. § 3730(b)(2) provides in full:

> A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(footnote omitted).

> Procrit for cancer patients that would increase sales and federal reimbursements by approximately a third. [OBP]'s scheme worked, and starting in around 1999 Medicare began reimbursing for Procrit at a one-third higher dosage than it had previously, without FDA approval for this dosage and contrary to the Medicare Act's rules for reimbursement of cancer drugs. The injury to the Medicare program alone is in the hundreds of millions.

The Information then went on to discuss this "scheme" in more detail.[4]

On July 12, 2005, after an investigation, the DOJ declined to intervene in the Original Complaint. On December 5, 2005, the Blair Complaint was voluntarily dismissed and subsequently unsealed in full.

On October 26, 2006, over OBP's objection, the district court allowed Duxbury's motion to amend the Original Complaint, and the next day, on October 27, 2006, both Relators filed a First Amended Complaint (the "Amended Complaint"). The Amended Complaint added Relator McClellan as a party and alleged three counts, two of which are at issue on this appeal.[5] (Am. Compl. ¶¶ 3, 227, 249, 270).

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[4] Duxbury asserts that the Blair Complaint had not been disclosed to him prior to the submission of the Information.

[5] Count II of the Amended Complaint alleges that OBP engaged in a scheme to publish a fraudulently inflated AWP for Procrit. On June 27, 2007, the parties jointly stipulated to the dismissal of this count.

Count I alleges that, beginning in December 1992 to the present, OBP engaged in a scheme to provide kickbacks to health care providers "to induce them to prescribe ProCrit." (Id. ¶¶ 228-232). The kickbacks allegedly included "free ProCrit, off-invoice discounts and cash in the form of rebates, consulting fees, educational grants, payments to participate in studies or trials, and advisory board honoraria." (Id. ¶ 228). The Amended Complaint alleges that the kickbacks, among other things, "caused providers and hospitals to submit false claims for payment to Medicare for ProCrit." (Id. ¶¶ 229, 243-244).

Count III alleges that, beginning in 1997, OBP unlawfully promoted "[t]he administration of ProCrit at 40,000 units 1X per week to oncology patients," which "was not approved by the FDA." (Id. ¶¶ 131, 271, 273). Thus, the Amended Complaint alleges that OBP's "inflated dosing scheme was a substantial factor causing the submission of false claims for payment for ProCrit," insofar as OBP "caused providers and hospitals to administer ProCrit to chemotherapy patients at 40,000 units 1X/week[], and in the absence of [OBP's] scheme they would have administered ProCrit at 10,000 IU 3X/week." (Id. ¶ 282).

### C. The Dismissal of the Amended Complaint

On January 17, 2007, OBP moved to dismiss the Amended Complaint for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) and, in the alternative, for failure to plead fraud with particularity under Federal Rule of Civil Procedure 9(b). On January 28, 2008, the district court allowed OBP's motion to dismiss with prejudice and entered judgment in OBP's favor. See United

States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 551 F. Supp. 2d 100 (D. Mass. 2008).

As to Count I, the district court first held that the kickback claims were "based upon" a "public disclosure," in this case the "allegations" contained in the MCC filed in the AWP MDL, which also alleged the use of illegal kickbacks. See id. at 105- 08. The district court further held that Duxbury "qualifies as an original source" for the kickback claims, but only for those claims that occurred during his period of employment, 1992 through 1998, since "his direct knowledge of OBP's activities only extends to the time he was employed by the company." Id. at 109. Having established its subject matter jurisdiction, the court nevertheless dismissed the 1992 through 1998 kickback claims because the Amended Complaint failed to plead the claims with sufficient particularity under Rule 9(b). Id. at 115-16.

As to the kickback claims from 1998 to the present, the district court held that McClellan did not qualify as an "original source," as the Amended Complaint did not sufficiently allege that McClellan offered information concerning the kickback claims to the government prior to the filing of the Original Complaint. Id. at 109-10. Relatedly, and in the alternative, the district court found that, even if McClellan qualified as an original source, his claims were barred by the "first-to-file" bar because he asserted his kickback claims after the filing of the Original Complaint. Id. at 110.

As to Count III, the court dismissed the claims concerning "off-label" promoting because they were barred by the "first-to-file" rule. Id. at 110-14. The district court first held that, even though Paragraphs

40 through 42 of the Original Complaint mentioned unlawful off-label promotion, the Original Complaint did "not provide the essential facts regarding a widespread scheme to promote off-label uses of Procrit." Id. at 114. Thus, the district court considered the Blair Complaint the "'first' complaint to allege claims based upon OBP's alleged off-label marketing of Procrit," and accordingly dismissed the off-label promoting claims in Count III of the Amended Complaint. Id.

As no claims survived, the district court dismissed the Amended Complaint with prejudice as to the Relators. Relators now appeal.

## II. Discussion

The district court dismissed a portion of Count I and all of Count III for lack of subject matter jurisdiction. Thus, "[w]e review the district court's determination that it lacked subject matter jurisdiction de novo." Muskat v. United States, 554 F.3d 183, 194 (1st Cir. 2009). Subject matter jurisdiction in this case is based on the allegations contained in the Amended Complaint. See Rockwell, 549 U.S. at 473. Accordingly, "we take as true all well-pleaded facts in the [Amended Complaint], scrutinize them in the light most hospitable to the plaintiffs' theory of liability, and draw all reasonable inferences therefrom in the plaintiffs' favor." Fothergill v. United States, 566 F.3d 248, 251 (1st Cir. 2009), see also id. at 251 n.1 (noting that "[t]his standard applies to motions to dismiss for want of subject-matter jurisdiction that are adjudicated on the pleadings, in advance of jurisdictional discovery and without the taking of any evidence."). "[W]e may affirm an order of dismissal on any ground made

apparent by the record (whether or not relied upon by the lower court)." Aguilar v. U.S. Immig. & Customs Enf., 510 F.3d 1, 8 (1st Cir. 2007).

The district court dismissed the remaining portion of Count I under Federal Rule of Civil Procedure 9(b) for failure to plead fraud with sufficient particularity. We similarly "review de novo the district court's dismissal order for failure to comply with Rule 9(b)." United States ex rel. Gagne v. City of Worcester, 565 F.3d 40, 45 (1st Cir. 2009).

**A. Count I**

The Relators contend that the district court erred in dismissing the kickback claims contained in Count I, which the court dismissed, in part, based on the "public disclosure" bar, and, in part, based on Rule 9(b).

"The threshold question in a False Claims Act case is whether the statute bars jurisdiction." Rost, 507 F.3d at 727. The district court's dismissal of the kickback claims turns on the "public disclosure" bar, set forth at 31 U.S.C. § 3130(e)(4). It provides:

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or [General] Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(A) & (B) (emphasis added).

As we discussed in Rost, analysis of the "public disclosure" bar "requires several inquiries":

> (1) whether there has been public disclosure of the allegations or transactions in the relator's complaint;
>
> (2) if so, whether the public disclosure occurred in the manner specified in the statute;
>
> (3) if so, whether the relator's suit is "based upon" those publicly disclosed allegations or transactions; and
>
> (4) if the answers to these questions are in the affirmative, whether the relator falls within the "original source" exception as defined in § 3730(e)(4)(B).

507 F.3d at 728. On appeal, the Relators do not challenge the district court's holding that the kickback claims contained in Count I are "based upon the public disclosure of allegations . . . in a . . . civil . . . hearing," in this case the allegations of illegal kickbacks contained in the MCC filed in the AWP MDL. Thus, we turn our attention to the fourth question, whether the Relators fall within the "original source" exception as defined in § 3730(e)(4)(B).

### 1. The "Provided" Language in the Original Source Exception

On appeal, OBP and the United States, appearing as an amicus, propose an alternative ground to affirm the dismissal of Count I. Under the FCA, an "original source" is defined as:

> an individual who has [1] direct and independent knowledge of the information on which the allegations are based and [2] has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(B) (emphasis added). In determining whether the Relators qualified as original sources, the district court held that "[t]he plain language of the FCA only requires the relator to provide his information to the government prior to filing his action," and that "[t]his unambiguous statutory language must guide the court's interpretation." Duxbury, 551 F. Supp. 2d at 109.

Both OBP and the United States argue that this was error, and contend that 31 U.S.C. § 3730(e)(4)(B) requires a relator to provide the information to the government before the public disclosure itself, not just before the filing of the relator's suit. As there is no allegation in the Amended Complaint that either McClellan or Duxbury provided any information concerning their kickback claims to the government prior to the public disclosure of the kickback allegations in the AWP MDL, both OBP and the government contend that we can affirm the dismissal of the kickback claims on this alternative ground. As explained in more detail below, and after a careful

analysis of the FCA, we disagree, and conclude that the district court's interpretation is the correct one.

We have not addressed the meaning of "provided the information to the Government before filing an action" under § 3730(e)(4)(B), but the issue has divided the courts. The Fourth Circuit, consistent with the district court, has held that § 3730(e)(4)(B) "requires only that the relator . . . voluntarily provide the information to the government before filing his qui tam action." United States ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1351 (4th Cir. 1994) (emphasis in original). The Second and Ninth Circuits have outlined a second approach, holding that the relator "must have directly or indirectly been a source to the entity that publicly disclosed the allegations on which a suit is based." United States ex rel. Dick v. Long Island Lighting Co., 912 F.2d 13, 16 (2d Cir. 1990); see also United States ex rel. Wang v. FMC Corp., 975 F.2d 1412, 1419 (9th Cir. 1992). The D.C. and Sixth Circuits have taken a third approach that stakes out a middle ground, holding that "an 'original source' must provide the government with the information prior to any public disclosure," but not requiring the relator to be the cause of the public disclosure. United States ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 690 (D.C. Cir. 1997); see also United States ex rel. McKenzie v. BellSouth Telecomms., Inc., 123 F.3d 935, 942-43 (6th Cir. 1997). OBP and the United States urge us to take this middle approach.

Although we are about to travel a well-trodden path, our first step remains the same. "Our first step in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the

case." Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997). "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." Id. at 341.

By its terms, the "original source" exception only requires the relator to "provide[] the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(e)(4)(B). Section 3730(e)(4)(B) does not impose any other timing requirement. Nor does § 3730(e)(4)(A). Thus, like the Fourth Circuit and the district court below, we conclude that the plain terms of § 3730(e)(4)(B) begin and end the matter. See Robinson, 519 U.S. at 340 ("Our inquiry must cease if the statutory language is unambiguous and 'the statutory scheme is coherent and consistent.'" (quoting United States v. Ron Pair Enters., Inc., 489 U.S. 235, 240 (1989))).

The government argues that the language of § 3730(e) (4)(B), when read in context, supports its view. Following the D.C. Circuit, the government points to the meaning of the terms "original source" itself, contending that a "source" is defined as "[t]he originator or primary agent of an act, circumstance, or result." Black's Law Dictionary 1522 (9th ed. 2009) (using the example "she was the source of the information."). Thus, a source cannot "originat[e]" information that has been publicly disclosed. The D.C. Circuit similarly found significance in "Congress's decision to use the term 'original source' rather than simply incorporating subparagraph (B)'s description into subparagraph (A)." Findley, 105 F.3d at 691.

However, we decline to rely upon the plain meaning of the terms "original source" when the statute defines the term at § 3730(e)(4)(B). It is only "[w]hen a word is not defined by statute" that we "construe it in accord with its ordinary or natural meaning." See Smith v. United States, 508 U.S. 223, 228 (1993). In addition, we decline to attribute significance to Congress's use of the terms "original source" rather than engraft the definition found at § 3730(e)(4)(B) into § 3730(e)(4)(A). Section 3730(e)(4)(A) sets forth two exceptions to the "public disclosure" bar, (1) when the relator is an "original source" and (2) when "the action is brought by the Attorney General." Thus, setting forth the definition of one of these exceptions in a separate subparagraph, rather than shoehorning it into § 3730(e)(4)(A), avoids unnecessary confusion and does not imply anything further. Finally, had Congress intended to retain the plain meaning of "original source" and require relators to provide their information prior to the public disclosure, "it easily could have done so." See Rost, 507 F.3d at 729 (rejecting argument that, for purposes of the meaning of "public disclosure," "equates the government with the public").

Typically, we end our review when "the plain language of a statute unambiguously reveals its meaning, and the revealed meaning is not eccentric." United States v. Meade, 175 F.3d 215, 219 (1st Cir. 1999) (noting that, in such circumstances, "courts need not consult other aids to statutory construction"). OBP and the government, however, argue that such an eccentricity would result.

Both OBP and the government primarily argue that interpreting the "provided" language in

§ 3730(e)(4)(B) by its plain terms would conflict with the intent of Congress. See United States v. Am. Trucking Ass'n, 310 U.S. 534, 542 (1940) ("In the interpretation of statutes, the function of the courts is . . . to construe the language so as to give effect to the intent of Congress."). Specifically, they argue that reading § 3730(e)(4)(B) by its plain terms would permit relators to bring suit based upon fraud that was already publicly disclosed, so long as the relator had "direct and independent knowledge" of the fraud. For example, a relator who learns about fraud against the government in the Huffington Post would be permitted to bring a qui tam suit "based upon" that "public disclosure" if she has "direct and independent knowledge" of the fraud and provides that information to the government before filing suit, literally the day before filing. The same would be true if the "public disclosure" resulted from a long-standing government investigation, where a relator would be entitled to bring suit so long as he or she had "direct and independent" knowledge of the public disclosure.

The D.C. Circuit concluded that, although the FCA provides financial incentives to provide information about fraud to the government, "[o]nce the information has been publicly disclosed, however, there is little need for the incentive provided by a qui tam action." Findley, 105 F.3d at 691. The Sixth Circuit discusses this point in more detail, holding that requiring a relator to disclose his or her information to the government prior to the public disclosure at issue advances the twin goals of (1) alerting the government to potential fraud and (2) creating incentives to do so as early as possible.

McKenzie, 123 F.3d at 942-43. As put by the Sixth Circuit,

> [T]his approach furthers Congress's . . . goal in amending the FCA: "[T]o prevent 'parasitic' qui tam actions in which relators, rather than bringing to light independently discovered information of fraud, simply feed off of previous disclosures of public fraud." Siller, 21 F.3d at 1347. Anyone who alerts the government and is a "true whistleblower" deserves any reward that may be obtained by pursuing a qui tam action under the FCA. However, the individual who sits on the sidelines while others disclose the allegations that form the basis of her complaint should not be able to participate in any award. This would be contrary to the purpose of the statute.

Id. at 943; see also Wang, 975 F.2d at 1419 ("Qui tam suits are meant to encourage insiders privy to a fraud on the government to blow the whistle on the crime. In such a scheme, there is little point in rewarding a second toot."). Thus, both OBP and the government argue that requiring the relator to provide his or her information before the public disclosure corrects this problem and ensures that only productive suits are filed, that is, those suits in which a "true whistleblower" alerts the government of fraud not publicly disclosed.

After careful consideration of the arguments in favor of adopting the middle approach, we conclude that honoring the plain and unambiguous meaning of § 3730(e)(4)(B) would not conflict with the intent of Congress. Our decision is supported by our own

review of the "language, structure, and history" of § 3730(e)(4)(B) and the "public disclosure" bar. See Rost, 507 F.3d at 728-29 (reviewing the language, structure and history of the terms "public disclosure" in rejecting interpretation that conflicted with the plain meaning of the statute). As we have just discussed the language of § 3730(e)(4)(B), we turn to the structure and history of the statute.

**i. Structure**

The structure of the FCA mitigates many of the concerns that lead the D.C. and Sixth Circuits to adopt the middle approach and, in fact, demonstrates that the middle approach has the potential to prohibit productive suits. As an initial matter, the "first-to-file" rule already provides potential relators significant incentive not to sit on the sidelines. As we discuss in more detail below, "a goal behind the first-to-file rule" is to provide incentives to relators to "promptly alert[] the government to the essential facts of a fraudulent scheme." United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1188 (9th Cir. 2001). It is unclear why a relator would wait for a public disclosure and risk another relator bringing suit.

Moreover, the Supreme Court's recent decision in Rockwell, which interpreted the "direct and independent" knowledge requirement of the public disclosure bar, substantially undercuts the conclusion by the D.C. and Sixth Circuits that "little incentive" is necessary for suits brought after a public disclosure. In addressing the meaning of the "direct and independent knowledge" requirement of the "original source" exception in § 3730(e)(4)(B), the Rockwell Court also addressed the meaning of the

term "information" found in both § 3730(e)(4)(A) and § 3730(e)(4)(B). It held that "information" for purposes of both subparagraphs refers to the "information underlying the allegations of the relator's action," not the information underlying the public disclosure. Rockwell, 549 U.S. at 472. The Court noted:

> Section 3730(e)(4)(A) bars actions based on publicly disclosed allegations whether or not the information on which those allegations are based has been made public. It is difficult to understand why Congress would care whether a relator knows about the information underlying a publicly disclosed allegation (e.g., what a confidential source told a newspaper reporter about insolid pondcrete) when the relator has direct and independent knowledge of different information supporting the same allegation (e.g., that a defective process would inevitably lead to insolid pondcrete). Not only would that make little sense, it would raise nettlesome procedural problems, placing courts in the position of comparing the relator's information with the often unknowable information on which the public disclosure was based. Where that latter information has not been disclosed (by reason, for example, of a reporter's desire to protect his source), the relator would presumably be out of court. To bar a relator with direct and independent knowledge of information underlying his allegations just because no one can know what information underlies the similar allegations of some other person simply makes no sense.

Id. at 471-72 (emphasis added).

Rockwell clarifies that the information that the original source has "direct and independent knowledge" of does not have to be the same as the information upon which the public disclosure is based. Thus, a public disclosure concerning governmental fraud resulting from a Huffington Post article may be based on information that is different (to use the example in Rockwell, "what a confidential source told a . . . reporter about insolid pondcrete") than the information a relator may have in support of the same fraud ("that a defective process would inevitably lead to insolid pondcrete"). See id. The same would be true of an ongoing governmental investigation, where the information upon which the government's public disclosures are based may be different from the information that the relator has in his possession.

But as a result of that clarification, Rockwell strongly suggests that situations can arise where the information upon which the public disclosure is based may be unavailable (such as a reporter protecting a source) or be of little value (if based on rumors), while a relator may have different information of the publicly disclosed fraud (such as eyewitness testimony, documents, etc.) of great significance. This has substantial plausibility when the public disclosure is based on the "news media," where sources may fear to come forward to serve as witnesses but others with "direct and independent knowledge" may be so willing. Although in such a situation, the relator, in a technical sense, is not a "true whistleblower," we disagree that such a relator does not "deserve[] any reward that may be obtained by pursuing a qui tam action under the FCA." See

McKenzie, 123 F.3d at 942-43. Thus, the approach taken by D.C. and Sixth Circuits has the potential to bar productive suits.

**ii. History**

The history of the "public disclosure" bar and the "provided" language under § 3730(e)(4)(B) also does not require us to deviate from the plain meaning. The legislative history of the "public disclosure" bar has been well rehearsed by this and other circuits. See, e.g., Prawer, 24 F.3d at 324-26; see also Findley, 105 F.3d at 679-81. We only discuss legislative history relevant to our inquiry here.

The "provided" language in § 3730(e)(4)(B) was specifically enacted to "'correct[]' the holding of United States ex rel. Wisconsin v. Dean." Findley, 105 F.3d at 691; See also Siller, 21 F.3d at 1354; FMC Corp., 975 F.2d at 1419 ("Seeking only to 'correct' opinions like Dean, Congress permitted one who publicly disclosed the information to bring a qui tam suit."). Dean was a 1984 Seventh Circuit decision decided prior to the 1986 amendments that resulted in the current "public disclosure" bar. The case concerned a previous jurisdictional bar, adopted in 1943, that barred relator suits "'based upon evidence or information in the possession of the United States . . . at the time such suit was brought.'" Findley, 105 F.3d at 680 (omission in original) (quoting Act of December 23, 1943, 57 Stat. 608, recodified in 31 U.S.C. § 3730(b)(4) (1982) (superseded)). The 1943 jurisdictional bar provided no exception for when "the relator was the source of that information," although such an exception was proposed. Id. "In Dean, the Seventh Circuit was faced with the question of whether the State of

Wisconsin should be allowed to act as a qui tam relator in a Medicaid fraud action where the State, in accordance with the federal regulations, had already reported the fraud to the federal court." Prawer, 24 F.3d at 325 (citing United States ex rel. Wisconsin v. Dean, 729 F.2d 1100, 1102-04 (7th Cir. 1984)). The Dean court answered in the negative, stating that "[i]f the State of Wisconsin desires a special exemption to the False Claims Act because of its requirement to report Medicaid fraud to the federal government, then it should ask Congress to provide that exemption." 729 F.2d at 1106.

Congress obliged, and in 1986 Congress amended the FCA to "'encourage more private enforcement suits.'" Findley, 105 F.3d at 680 (quoting S. Rep. No. 93-345, at 23-24 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5288-89); see also Rost, 507 F.3d at 730 (same). As emphasized by the Sixth Circuit, one goal of the amendments was to "prevent 'parasitic' qui tam actions in which relators, rather than bringing to light independently discovered information of fraud, simply feed off of previous disclosures of fraud." McKenzie, 123 F.3d at 943 (quoting Siller, 21 F.3d at 1347).

But two additional changes are relevant here. The first was to abolish the "government knowledge" regime entailed by the 1943 jurisdictional bar, which Congress concluded "proved too restrictive of qui tam actions, resulting in the under-enforcement of the FCA." Rost, 507 F.3d at 729. Congress replaced the "government knowledge" regime with one, as shown by the "public disclosure" bar, focused on the "public disclosure of information given to the government." Id. As put by the D.C. Circuit, "Congress thus changed the focus of the jurisdictional bar from

evidence of fraud inside the government's overcrowded file cabinets to fraud already exposed in the public domain." Findley, 105 F.3d at 684. To replace the "government knowledge" bar, Congress "'broadened the universe of potential [qui tam] plaintiffs, with only four exclusions' enumerated in § 3730(e)." Rost, 507 F.3d at 730 (quoting United States ex rel. LeBlanc v. Raytheon Co., 913 F.3d 17, 19 (1st Cir. 1990)).

The second was to reinstate the "original source" exception proposed, but not adopted, in 1943, so as to avoid the situation in Dean where a potential relator who provided information to the government was not barred from bringing a qui tam suit. It is this second change that the "provided" language sought to remedy, by allowing individuals to maintain suit and "provide their information to the government." As put by the Fourth Circuit:

> To "correct" Dean only required that Congress adopt language that would ensure that a plaintiff who had provided his information to the government would not be barred from bringing a qui tam action on the ground that the government already possessed the information. This it did in section 3730(e)(4)(B), by providing that a plaintiff who produces his independently-obtained information to the government is excepted from section 3730(e)(4)(A)'s jurisdictional bar.

Siller, 21 F.3d at 1354.

The second additional change provides a direct justification of the "provided" language in § 3730(e)(4)(B), but it is the first that has been glossed over. Both the D.C. Circuit and the Sixth

Circuit have focused on the concern with "parasitic" suits, concluding that any such suit brought after a "public disclosure" was necessarily "parasitic." As noted above, we question that conclusion. But we also note that the 1986 amendments equally sought to end a regime that resulted in the "under-enforcement" of the FCA, one that rested too much on government notice to prevent fraud. As we have noted, Congress "amended the statute to 'encourage more private enforcement suits.'" Rost, 507 F.3d at 730 (quoting S. Rep. No. 93-345, at 23-24). Although we have recognized that a "public disclosure" regime has the benefit, one lacking in a "government notice" regime, of providing "public pressure" on the government to act, see Rost, 507 F.3d at 730, there also may arise situations when even that is not enough, and the government would benefit from suits brought by relators with substantial information of government fraud even though the outlines of the fraud are in the public domain.

The D.C. Circuit was quite explicit that its approach "may on occasion prevent qui tam lawsuits that may not be truly 'parasitic.'" Findley, 105 F.3d at 685. However, we have rejected readings of the "public disclosure" bar that "would create a new exclusion not articulated in the text" which would discourage "productive private enforcement." See Rost, 507 F.3d at 730. In Rost, we rejected an interpretation of "public disclosure" under § 3730(e)(4)(A) to include self-disclosures made by a private party only to government agencies without further disclosure, as it would "reinstate exactly what Congress eliminated -- the 'government knowledge' bar." Id. Although the reading urged here would not return us to the "government notice"

regime, it is overbroad so as to prohibit cases that are "productive private enforcement suits." Thus, just as we eschewed reading an exclusion in Rost that did not have textual support and resulted in discouraging "productive private enforcement," we similarly decline to do so here.

We conclude by emphasizing that we are cognizant of our institutional role and the limits of our competence in interpreting the FCA. As noted by the Fourth Circuit, in criticizing the approaches taken by the Second and Ninth Circuit:

> It strikes us as especially inappropriate (not to mention frighteningly treacherous) to attempt, as these courts have done, to distill from such broad, generalized objectives, the answers to the kind of specific statutory questions that we herein address; fine calibrations are just not possible through the use of such crude instruments. This is particularly so in this context, given that, although we can perhaps divine from these abstract purposes a congressional intention to balance the need to encourage qui tam actions against the need to prevent parasitic suits, we can discern virtually nothing as to precisely how Congress ultimately believed it achieved that balance. If the language of law is to have any meaning at all, then surely it must prevail over the kind of speculation that is entailed in such an enterprise as these courts have undertaken.

Siller, 21 F.3d at 1354-55. We agree. The FCA has many moving parts, so that any attempt by us to move one may upset others. Given the difficulty in determining the right "balance," we conclude that

the better approach is to rely upon the plain and unambiguous language of § 3730(e)(4)(B) in the absence of any clear direction to do otherwise.

Thus, we reject OBP's and the government's contention that § 3730(e)(4)(B) requires an "original source" to provide his or her information before the public disclosure at issue. Instead, we will honor the plain and unambiguous terms of the statute, and hold that § 3730(e)(4)(B) only requires that a relator provide his or her information prior to the filing of the qui tam suit.

2. McClellan

The Relators contend that the district court erred in holding that McClellan failed to qualify as an original source. We disagree. As an initial matter, the Amended Complaint alleges that "Relator McClellan does not bring any new legal claims against [OBP], but rather adds additional supporting facts to the legal claims previously made [in the Original Complaint]." (Am. Compl. ¶ 28). Thus, the district court correctly concluded that McClellan was required, in order to qualify as an "original source," to provide his information prior to the filing of the Original Complaint, rather than the Amended Complaint. See Duxbury, 551 F. Supp. 2d at 109.

Although the Amended Complaint alleges that "[b]oth Relators have direct and independent knowledge of information on which the allegations are based, and have provided such information to the United States before filing suit, as required by 31 U.S.C. § 3730(e)(4)," (Am. Compl. 16), the district court noted that Duxbury "proffered no support for this conclusory allegation" and the district court

refused to "reasonably infer it," as "Duxbury did not move to add McClellan as a relator until October 2006." Id. at 110. We agree.

McClellan counters that we are required to "take as true all well-pleaded facts in [the] complaint[]" and "draw all reasonable inferences therefrom in [his] favor." See Fothergill, 566 F.3d at 251. However, we are under no obligation to credit McClellan's conclusory allegations, which simply parrot the elements of the statute. See Rodriguez v. SK & F Co., 833 F.2d 8, 8 (1st Cir. 1987) (per curiam) (affirming dismissal for lack of subject matter jurisdiction where "the plaintiff has failed to allege grounds upon which to support either his conclusory allegation of diversity jurisdiction or federal question jurisdiction."); cf. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (in reviewing a motion to dismiss for failure to state a claim, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.").

We also refuse to "reasonably infer" McClellan's allegation concerning disclosure. On appeal, McClellan points to a single allegation in the Original Complaint that he "had over 400 Patient Trial Cards in his possession in one time." (Compl. ¶ 39). This allegation does not support an allegation that he provided his information about the kickback claims prior to the filing of the Original Complaint. McClellan also points to the Information, which was provided to the government after the filing of the Original Complaint. The Information provides significant detail concerning the Relators' off-label

promotion claims, not its kickback claims, and thus the Information also provides no support for his allegation that he provided his information prior the filing of the Original Complaint.

For the above reasons, we hold that the district court did not err in holding that McClellan did not qualify as an "original source" under § 3730(d)(1), and thus affirm the dismissal of those kickback claims attributable to McClellan. Accordingly, we do not need to address the district court's alternative ground for dismissing the claim, that those kickback claims attributable to Duxbury are barred by the "first-to-file" rule.

### 3. Duxbury

We finally address the dismissal of Duxbury claims under Rule 9(b). Duxbury seeks reversal. We agree.

In applying Rule 9(b), the district court held that the rule "requires relators to 'provide details that identify particular false claims for payment that were submitted to the government.'" Duxbury, 551 F. Supp. 2d at 114 (quoting Rost, 507 F.3d at 731) (emphasis added). This was error. In Rost, we noted a distinction between a qui tam action alleging that the defendant made false claims to the government, and a qui tam action in which the defendant induced third parties to file false claims with the government. 507 F.3d at 732 (noting that latter action is "in a different category" than former).[6] In the latter

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[6] Although this distinction resembles the distinction between "subsection (a)(1)" claims, which have a presentment (continued...)

context, we held that a relator could satisfy Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility" without necessarily providing details as to each false claim. Rost, 507 F.3d at 733; see also United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009) (holding that FCA claims under Rule 9(b) "may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.").

Similar to this case, Rost concerned allegations that "false claims were allegedly submitted by doctors who were allegedly induced and seduced by defendants into prescribing Genetropin for off-label uses to their patients, including federally insured patients." Id. at 732. We acknowledged that "Rost's complaint amply describes illegal practices in which Pfizer allegedly engaged." Id. However, "[a]s presently pled, the complaint d[id] not sufficiently establish that false claims were submitted for

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requirement, and "subsection (a)(2)" claims, which do not, see Gagne, 565 F.3d at 44-45, our analysis in Rost applied equally to both (a)(1) and (a)(2) claims. See Rost, 507 F.3d at 731-32 (noting that relator there asserted both (a)(1) and (a)(2) claims); see also id. at 733 (rejecting a claim that (a)(2) claims should be treated differently, noting that "[o]ur analysis -- which recognizes the role played by third parties other than Pfizer in submitting claims and making statements to the government -- undermines Rost's § 3729(a)(2) argument as well"). Here, as in Rost, Duxbury asserts both (a)(1) and (a)(2) claims. (See Am. Compl. Count I).

government payment in a way that satisfies the particularity requirement." Id. at 733. We noted:

> It may well be that doctors who prescribed Genotropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed Genotropin for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it. Rost did not plead enough to satisfy the concerns behind Rule 9(b).

Id.

Here, as in Rost, Duxbury does not allege that OBP itself submitted false claims to the government, but that, through OBP's illegal kickbacks, false claims to the Medicare Program were filed by medical providers for reimbursement of Procrit purchases. However, unlike in Rost, Duxbury does more than "suggest fraud was possible." Id. at 733. Duxbury sets forth allegations of kickbacks provided by OBP that resulted in the submission of false claims by eight healthcare providers in the Western United States: (1) St. Joseph's Hospital in Tacoma, Washington (Am. Compl. ¶ 211a); (2) Rainier Oncology of Puyallap, Washington (Am. Compl. ¶ 211b); (3) Memorial Clinic in Olympia, Washington (Am. Compl. ¶ 211c); (4) Western Washington Cancer Treatment Center (Am. Compl. ¶ 211d); (5) Mid Columbia Kidney Center in Kennewick, Washington (Am. Compl. ¶ 211e); (6) St. Peter's Hospital in Olympia, Washington (Am. Compl. ¶ 211f); (7) Memorial Clinic Oncology Group in

Washington (Am. Compl. ¶ 211g); (8) Swedish Hospital in Seattle, Washington (Am. Compl. ¶ 211h). As to each, Duxbury provides information as to the dates and amounts of the false claims filed by these providers with the Medicare program. One such allegation is instructive:

> In 1997-98 Western Washington Treatment Center in Olympia, Washington received more than $5,000 of free commercially packaged ProCrit from [OBP] under the direction of Robert Ashe so that Western Washington could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. [OBP] intended the free commercially packaged ProCrit to be a "cash equivalent" "kickback" to Western Washington in order to induce the provider to purchase ProCrit and to administer ProCrit at the "off-label" once a week dosing regimen. Western Washington was reimbursed by Medicare for the free commercially packaged ProCrit. As a result, [OBP] knowingly caused the presentation by Western Washington of these false claims to the United States Government.

(Am. Compl. ¶ 211d). Duxbury provides more specifics with respect to other medical providers. As to St. Joseph's Hospital, Duxbury alleges that the hospital submitted "approximately 4,800 claims a month for Medicare reimbursement" based upon OBP's unlawful kickbacks. (Am. Compl. ¶ 211a).

Although a close call, Duxbury's claims satisfy Rule 9(b) under this "more flexible standard." See

Gagne, 565 F.3d at 46. Although Duxbury does not identify specific claims, he has alleged the submission of false claims across a large cross-section of providers that alleges the "the who, what, where, and when of the allegedly false or fraudulent representation." See Rodi v. So. New England Sch. of Law, 389 F.3d 5, 15 (1st Cir. 2004) (quotation omitted); see also Rost, 507 F.3d at 731 (noting that Rule 9(b) requires a plaintiff to allege "'the time, place, and content of an alleged false representation.'" (quoting Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir. 1996))). In particular, Duxbury has identified, as to each of the eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves.

Moreover, as to his (a)(2) claims, Duxbury has also alleged facts with respect to the medical providers he identifies that support his claim that OBP intended to cause the submission of false claims. See Allison Engine, 128 S. Ct. at 2126 (holding that an action under subsection (a)(2) requires a relater to allege "that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim"); see also Gagne, 565 F.3d at 47 (affirming dismissal of an (a)(2) claim under Rule 9(b) where "[r]elators fail to connect the only falsity or fraud for which they provide any detail").

With respect to Western Washington, Duxbury alleges that "Washington received more than $5,000 of free commercially packaged ProCrit from [OBP] . . . so that Western Washington could submit the free product for reimbursement to Medicare under

the false and fraudulent certification that the provider had paid for the product," and that "Western Washington was reimbursed by Medicare for the free commercially packaged ProCrit." (Am. Compl. ¶ 211d) (emphasis added). The same is true of the other medical providers. See, e.g., id. 211a ("[OBP] intentionally failed to report these payments to the US Government in order to keep secret the profit spread between the rate upon which Medicare reimbursed medical providers like St. Joseph's for ProCrit."); id. ¶ 211b ("Ranier Oncology . . . was provided more than $20,000 of free commercially packaged ProCrit from [OBP] . . . under the guise of running an unlawful mini-trial so that Rainier Oncology could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product."); id. ¶ 211c ("Memorial Clinic . . . was provided approximately $15,000 of free commercially packaged ProCrit from [OBP] so that Memorial Clinic could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product."); id. ¶ 211e ("Mid Columbia Kidney Center . . . submitted claims to Medicare and was subsequently reimbursed by Medicare approximately $75,000 for the administering of ProCrit to Mid Columbia Kidney Center patients. . . . [OBP] provided Mid Columbia Kidney Center with an 'off-invoice' rebate of 5-8% for the purchase of ProCrit. [OBP] intentionally failed to report those 'off-invoice' rebates in order to keep secret the 'profit spread' between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread."); id. ¶ 211f ("St. Peter's Hospital . . . submitted claims to

Medicare for approximately two million dollars of ProCrit. St. Peter's contract with [OBP] provided St. Peter's with an 'off-invoice' rebate of 14% for the purchase of ProCrit. [OBP] intentionally failed to report to the U.S. Government these 'off-label' rebates in order to keep secret the 'profit spread' between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread."); id. ¶ 211g ("Memorial Clinic Oncology Group . . . purchased $750,000 of ProCrit. Memorial Clinic Oncology Group's agreement with [OBP] provided Memorial Clinic Oncology Group with an 'off-invoice' rebate of 5% for the purchase of ProCrit. [OBP] intentionally failed to report to the US Government the 'off-invoice' rebates in order to keep the 'profit-spread' between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread."); id. ¶ 211h ("Swedish Hospital . . . was given cash in the form of a so-called 'unrestricted educational grant' in the amount of approximately $15,000 [which was a kickback]. Provider subsequently purchased over $100,000 of ProCrit of which approximately 50% was submitted for Medicare reimbursement.").

Unlike in Rost, where the allegations gave rise to only speculation as to whether the alleged scheme caused the filing of false claims with the government, Duxbury has alleged facts that false claims were in fact filed by the medical providers he identified, which further supports a strong inference that such claims were also filed nationwide. We thus have allegations of "factual . . . evidence to strengthen the inference of fraud beyond possibility." Rost, 507 F.3d at 733.

Although we find that the factual evidence alleged here of the submission of false claims caused by OBP at a cross-section of medical providers, is sufficient in this context, "[w]e decline to draft a litigation manual full of scenarios" of what allegations would be sufficient for purposes of Rule 9(b). LeBlanc, 913 F.2d at 20 (discussing "original source" exception). "Suffice it to say that we limit our holding to the facts." Id. Accordingly, we conclude that Duxbury's allegations pass muster for purposes of Rule 9(b).

Thus, we hold that the kickback claims attributable to Duxbury, from the years 1992 through 1998, satisfied Rule 9(b). As the district court has jurisdiction over these claims since Duxbury established himself as an "original source," we reverse the dismissal of these claims.[7]

### B. Count III

The Relators contend that the district court erred in dismissing the "off-label" promotion claims contained in Count III. The district court relied upon

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[7] OBP urges other alternative grounds for affirming the dismissal of the Duxbury kickback claims. We deal with them briefly. OBP first claims the statute of limitations bars most of Duxbury's kickback claims. As the district court has not addressed the issue, we leave it to the district court to address it in the first instance. OBP also argues that the district court abused its discretion in permitting Duxbury to serve the Original Complaint outside the 120-month window mandated by Federal Rule of Civil Procedure 4(m) and D. Mass. Local Rule 4.1(b). We identify no abuse of discretion.

the "first-to-file" bar, which provides that "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The Blair Complaint, filed nearly a year before the Amended Complaint, also alleged a similar "off-label" promotion claim. Accordingly, the district court examined whether the Original Complaint, filed a month before the Blair Complaint, sufficiently alleged an "off-label" claim to be considered the first-filed complaint for purposes of the "first-to-file" bar. Duxbury, 551 F. Supp. 2d at 110-11. After carefully considering the allegations contained in both complaints, the district court concluded that, despite some similarities, the Original Complaint did "not provide the essential facts regarding a widespread scheme to promote off-label uses of Procrit." Id. at 114 (emphasis added). We agree.

As the Ninth Circuit has noted, "a goal behind the first-to-file rule" is to provide incentives to relators to "promptly alert[] the government to the essential facts of a fraudulent scheme." Lujan, 243 F.3d at 1188. All courts that have addressed the issue have interpreted § 3730(b)(5) to bar "a later allegation [if it] states all the essential facts of a previously-filed claim" or "the same elements of a fraud described in an earlier suit." United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 232-33 (3d Cir. 1998) (emphasis added); see also United States ex rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 217-18 (D.C. Cir. 2003) (holding that "§ 3730(b)(5) bars any action incorporating the same material elements of fraud as an action filed earlier" and "reject[ing] another possible test, one barring claims based on 'identical

facts.'"); Lujan, 243 F.3d at 1188-89 (following LaCorte, and rejecting an "identical facts" test). Under this "essential facts" standard, § 3730(b)(5) can still bar a later claim "even if that claim incorporates somewhat different details." LaCorte, 149 F.3d at 232-33. We take the same approach.

The Relators contend that the Original Complaint, in particular, Paragraphs 40 through 42, allege all of the "essential facts" of the off-label promotion scheme. As the district court found, there are significant similarities between the "off-label" promotion allegations contained in those paragraphs and the allegations in the Blair Complaint. Both allege that OBP did not have FDA approval for "a dosing regimen of 40,000 units once per week." (Compare Original Compl. ¶¶ 40(c), 41; Blair Compl. ¶¶ 22-27). Both allege that OBP promoted this dosage in order to "increase . . . payments for each Medicare Beneficiary receiving Procrit for treatment." (See Original Compl. ¶¶ 40(c), 41; Blair Compl. ¶¶ 22-27). And both allege that the higher dosage resulted in the filing of false claims with the government. See Duxbury, 551 F. Supp. 2d at 113 (noting these similarities).

However, the Original Complaint and Blair Complaint differ in one crucial respect. As recognized by the district court, the Blair Complaint contained a number of allegations that discuss, in significant detail, OBP's promotion of the "off-label" use, and alleged such "promotion" efforts as

> (1) direct off-label marketing to medical professionals; (2) influencing the results of purportedly independent clinical studies; (3) illegal payments to medical professionals in

> the form of "educational grants" and "clerkships;" (4) payments to medical professionals for giving presentations on increased dosage of Procrit; or (5) attending consulting conferences sponsored by OBP which pushed increased dosage of Procrit; and (6) rebate programs offered to induce increased prescriptions of Procrit.

Id. at 113 (citing Blair Compl. ¶¶ 27, 28-79). By contrast, Paragraphs 40 through 42 of the Original Complaint only allege one method by which OBP promoted the "off-label" use of Procrit, the use of "clinical trials," and, in particular, an unnamed "Phase IV Study" that "resulted in Medicare Part B paying for 40,000iu/week of Procrit in cancer chemotherapy patients instead of 30,000iu/week -- an increase in 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia." (Compl. ¶ 40(c)). As this allegation fails to encompass the other allegations contained in the Blair Complaint concerning OBP's "off-label" promotion, it fails to allege the "essential facts" of the "off-label" promotion scheme contained in the Blair Complaint. In fact, the Original Complaint nowhere refers to a "off-label" promotion scheme. Thus, we conclude that the Original Complaint cannot trump the Blair Complaint for purposes of the "first-to-file" rule.

On appeal, the Relators argue that the Information, which the Relators provided to the DOJ in response to its inquiries concerning the allegations contained in the Original Complaint, provided further allegations that covered the "essential facts" contained in the Blair Complaint. We have previously held that, in reviewing a dismissal for

lack of jurisdiction, "we need not confine our jurisdictional inquiry to the pleadings, but may consider those other materials" in the district court record. Aguilar, 510 F.3d at 8. We decline to do so here. The "first-to-file" rule is "exception-free," Lujan, 243 F.3d at 1187, and does not permit us to consider the Information, which was provided after the filing of the Blair Complaint.[8] Had Duxbury wanted to include the allegations contained in the Information, he had his opportunity to do so when he filed the Original Complaint seven months earlier.

For the above reasons, the district court did not err in dismissing Count III.

## III. Conclusion

For the foregoing reasons, we affirm the dismissal of all claims except those kickback claims attributable to Duxbury. For these latter claims, we reverse the dismissal and remand for further proceedings consistent with this opinion.

**Affirmed in part, Reversed in part and Remanded.**

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[8] We also note that the Information was produced after the Blair Complaint was made available to the Relator Duxbury, although the Relators contend that Duxbury had not yet received the Information.

## APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 03-12189-RWZ

UNITED STATES OF AMERICA *ex rel.*
MARK EUGENE DUXBURY and DEAN
McCLELLAN

v.

ORTHO BIOTECH PRODUCTS, L.P.

MEMORANDUM OF DECISION AND ORDER

January 28, 2008

ZOBEL, D.J.

Relators Mark Duxbury ("Duxbury") and Dean McClellan ("McClellan") (collectively, "Relators") have filed this action against defendant Ortho Biotech Products, L.P. ("OBP") under the qui tam provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3730, which permits a private person to file an action on behalf of the United States. The case is before me on defendant's motion to dismiss. For the reasons discussed below, the motion is allowed.

### I. Procedural History

Duxbury originally filed this action in November 2003. The FCA requires that the relator file his action under seal, during which time the United

States may investigate and evaluate the allegations and determine whether to intervene in the action. 31 U.S.C. § 3730(b)(2). On July 12, 2005, the United States gave notice of its declination to intervene, and the court ordered Duxbury to serve defendant. After a succession of requests for extensions, defendant was served on October 12, 2006. Duxbury subsequently moved to amend the complaint as of right and add McClellan as a co-relator pursuant to Federal Rule of Civil Procedure 15(a). This court allowed the motion over defendant's objection, noting that defendant had not yet filed a responsive pleading, and although the amended complaint increased in size, it was "less clear that the proposed amendment adds entirely new violations" of the FCA. (Docket # 50, 2.) The amended complaint explicitly states:

> Relator Duxbury is the original source of the claims and allegations contained in the original Complaint and the Amended Complaint. Through the course of his investigation Relator Duxbury developed Relator McClellan as an additional Relator. Relator McClellan is an additional relator who provides additional supporting facts and information. Relator McClellan does not bring any new legal claims against Defendant, but rather adds additional supporting facts to the legal claims previously made.

(First Amended Complaint ("Am. Compl.") (Docket # 51-3) ¶ 28.) Defendant has moved to dismiss the amended complaint, arguing, inter alia, that this court lacks jurisdiction over the suit and that Relators have not pled their claims with the requisite particularity.

## II. Factual Background

### A. The FCA

The FCA prohibits false or fraudulent claims for payment to the federal government and permits civil actions based on such claims to be brought by the Attorney General or by private individuals acting in the government's name. 31 U.S.C. § 3730(a)-(b). When the individual brings a suit in the government's name, the individual is known as the "relator," and his action is a "qui tam" suit.[1] The FCA does not create a cause of action against all fraudulent conduct affecting the government. Rather, FCA liability attaches to a "false or fraudulent claim for payment" or to a "false record or statement [made] to get a false or fraudulent claim paid" by the government. 31 U.S.C. § 3729(a)(1)-(2); United States ex rel. Rost v. Pfizer. Inc., 507 F.3d 720, 727 (1st Cir. 2007).

The statute further limits the actions that may be brought in several ways, two of which are relevant for present purposes. First, when a private individual brings an FCA action, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). This so-called "first-to-file" rule operates to prevent

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[1] "Qui tam" is shorthand for "qui tam pro domino rege quam pro se ipso in hac parte seguitir," meaning "who pursues this action on our Lord the King's behalf as well as his own." Rockwell Int'l Corp. v. United States, --- U.S. ---, 127 S. Ct. 1397, 1403 n.2 (2007).

multiplication of FCA suits that could lead to duplicative awards covering the same behavior. United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 233-34 (3d Cir. 1998). Second, under the "public disclosure" bar, the court does not have jurisdiction over a private individual's action if his claims are "based upon" the "public disclosure" of allegations or transactions, unless the individual bringing the suit is an "original source" of the information. 31 U.S.C. § 3730(e)(4).[2]

The FCA's jurisdictional scheme serves two competing purposes. On one hand, it seeks "to inspire whistleblowers to come forward promptly with information concerning fraud so that the

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[2] The relevant provision states in total:

> (4)(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4).

government can stop it and recover ill-gotten gains." United States ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 685 (D.C. Cir. 1997). On the other hand, it attempts to discourage so-called "parasitic" suits, in which opportunistic plaintiffs sue based upon information already publicly disclosed or that they did not otherwise discover. United States ex rel. S. Prawer and Co. v. Fleet Bank of Maine, 24 F.3d 320, 326 (1st Cir. 1994). The FCA's qui tam provisions must be analyzed in the context of these twin goals. Id.

**B. Relators and Their Claims**[3]

Relator Duxbury was employed by defendant from 1992 to 1998, beginning as a Product Specialist and eventually becoming a Regional Key Account Specialist for OBP's Western Division Oncology sales force. Relator McClellan was employed by defendant from 1992 to 2004, beginning as a Product Specialist and eventually becoming a Territory Manager for OBP's Western Division Oncology sales force. In their positions, Relators were "responsible for the promotion and sale of [OBP's drug Procrit®[4]] for Defendant in the Western United States." (Am. Compl. ¶ 17.)

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[3] This subsection is drawn from allegations contained in Relators' First Amended Complaint (Docket # 51-3).

[4] Procrit® ("Procrit") is the brand name for epoetin alfa, a drug which is marketed by OBP and used to treat anemia caused by chemotherapy, chronic kidney disease, HIV infection, and blood loss from certain types of surgery.

The amended complaint alleges three separate violations of the FCA. First, Relators allege that beginning in 1992, OBP undertook a scheme to give kickbacks to providers and hospitals to induce them to prescribe Procrit. The kickbacks allegedly included free samples, off-invoice discounts, rebates, consulting fees, educational grants, payments to participate in studies or trials and advisory board honoraria. (Am. Compl. ¶ 228.) Relators allege that the kickbacks caused providers and hospitals to submit false claims for payment to Medicare. They claim that the time period of the false claims is from "December 1992 to the present." (Id. ¶ 232.)

Second, Relators allege that defendant engaged in a scheme to publish inflated "Average Wholesale Prices" for Procrit that did not represent a real average of the wholesale prices for the drug. The parties have jointly stipulated to the dismissal of this claim (see Docket # 79), and the court will not consider it further.

Third, Relators allege that defendant promoted off-label dosing of Procrit in violation of the Food, Drug and Cosmetic Act and used "sham drug trials" to falsify eligibility for Medicare reimbursement for off-label uses of the drug. (Am. Compl. ¶ 271.) Relators claim that the time period for this claim is from January 1998 to the present. (Id. ¶ 273.)

Defendants move to dismiss the First Amended Complaint in its entirety on the grounds that the court lacks jurisdiction under the FCA's public disclosure bar, that certain claims are barred by the "first-to-file" rule, and that plaintiffs have not pled fraud with the requisite particularity. Additionally,

defendants assert that the "off-label" claims fail to state violations of the FCA.

## III. Subject Matter Jurisdiction

A qui tam relator's qualification to bring a suit is an issue of subject matter jurisdiction. Rockwell Int'l Corp. v. United States, --- U.S. ---, 127 S. Ct. 1397, 1405-06 (2007). Jurisdiction is based upon Relators' amended complaint. Id. at 1409. Plaintiffs bear the burden of establishing that the court has jurisdiction to hear their claims. Murphy v. United States, 45 F.3d 520, 522 (1st Cir. 1995). The court treats all well-pleaded facts as true and indulges all reasonable inferences in favor of the plaintiff. Aversa v. United States, 99 F.3d 1200, 1210 (1st Cir. 1996). "In addition, the court may consider whatever evidence has been submitted, such as depositions and exhibits . . . ." Id. Statutes such as the FCA which confer jurisdiction on federal courts "are to be strictly construed, and doubts resolved against federal jurisdiction." United States ex rel. Precision Co. v. Koch Indus., Inc., 971 F.2d 548, 552 (10th Cir. 1992).

The FCA does not permit "jurisdiction in gross." Rockwell, 127 S. Ct. at 1410. Instead, the court must examine Relators' ability to assert each claim. Id. ("The plaintiff's decision to join all of his or her claims in a single lawsuit should not rescue claims that would have been doomed by section (e)(4) if they had been asserted in a separate action. And likewise, this joinder should not result in the dismissal of claims that would have otherwise survived." (quoting United States ex rel. Merena v. SmithKline Beecham Corp., 205 F.3d 97, 102 (3d Cir.

2000) (Alito, J.))). Accordingly, I will analyze the two remaining claims individually.

**A. Count I: Kickbacks**

Count I alleges a scheme to give kickbacks in the form of free samples, off-invoice discounts, rebates, consulting fees, educational grants, payments to participate in studies or trials and advisory board honoraria to providers and hospitals to induce them to prescribe Procrit. The parties disagree regarding whether the public disclosure bar prohibits this claim.

The FCA prohibits qui tam actions when the relator's allegations are "based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media . . . ." 31 U.S.C. § 3730(e)(4)(A). The jurisdictional inquiry under Section 3730(e)(4) proceeds in three steps. The court must determine: (1) whether the allegations or transactions have been publicly disclosed in a manner provided by the statute; (2) if so, whether the relator's suit is "based upon" those allegations or transactions; and (3) if the answer to both questions is yes, whether the relator falls within the "original source" exception to the jurisdictional bar. United States ex rel. O'Keefe v. Sverdup Corp., 131 F. Supp. 2d 87, 91 (D. Mass. 2001).

### 1. Public Disclosure

The widely accepted framework for determining whether a public disclosure of the qui tam complaint's allegations or transactions has occurred is set forth in United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 654-55 (D.C. Cir. 1994). As the court in Quinn explained, "if X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements." Id. at 654. A public disclosure has occurred when either: (1) an allegation of fraud has been made (Z); or (2) both of the "essential elements" of the fraud – "a misrepresented state of facts and a true state of facts" (X and Y) – are in the public domain. Id. at 655.

OBP asserts that the essential elements supporting Count I were publicly disclosed in prior civil litigation and various government and media reports prior to Duxbury filing his initial complaint in November 2003.[5] Although the First Circuit has not addressed the issue, "every court of appeal to have addressed the question has held that any information disclosed through civil litigation and on file with the clerk's office should be considered a

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[5] OBP does not suggest that the court consider public disclosures made during the period between the initial and amended complaints. See United States ex rel. Montgomery v. St. Edward Mercy Med. Ctr., No. 4:05-CV-00899, 2007 WL 2904111, at *8 (E.D. Ark. Sept. 28, 2007). However, because the public disclosures made prior to the filing of Duxbury's initial complaint are sufficient it is not necessary to consider subsequent disclosures.

public disclosure . . . for purposes of section 3730(e)(4)(A)." United States v. Northrop Corp., 59 F.3d 953, 966 (9th Cir. 1995) (quoting United States ex rel Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1350 (4th Cir. 1994) (collecting cases)); see also Walburn v. Lockheed Martin Corp., 431 F.3d 966, 974 (6th Cir. 2005); Quinn, 14 F.3d at 652.

The prior litigation in this instance is a multi-district litigation termed In re Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, Civ. No. 01-12257-PBS ("AWP MDL"), currently pending in this District. The AWP MDL includes both private class action suits and suits on behalf of various States and other Medicare and Medicaid payors against a large number of pharmaceutical manufacturers. Plaintiffs in the AWP MDL filed a Master Consolidated Class Action Complaint ("MCC") in September 2002, more than a year before Duxbury filed his qui tam complaint in November 2003. (MCC (AWP MDL Docket # 148), Sept. 6, 2002.)) The MCC alleged that OBP and its co-defendants engaged in widespread fraudulent conduct, including kickbacks, improper use of free samples, discounts, rebates and "other hidden and improper inducements and price reductions." (See MCC ¶¶ 108-09, 131, 153, 162-172, 294-98.)

Relators argue that the MCC did not publicly disclose OBP's alleged fraud because (1) "it only revealed the component of Ortho's scheme that involved consumers, insurers and third party payers but not the manipulation of the Medicare reimbursement system," and (2) "it did not contain elements of the scheme of having Ortho's sales force intentionally cause the submission of false claims to the Government." (Relators' Mem. in Opp. to Def.'s

Mot. to Dismiss (Docket # 65), 20.) These arguments are strained, to say the least. Allegations regarding reimbursement by Medicare Part B based upon published Average Wholesale Prices ("AWPs") are a central component of the MCC, to the point that the MCC expends numerous paragraphs describing the Medicare insurance and reimbursement system and the impact of allegedly inflated AWPs on this system. (See, e.g., MCC ¶¶ 3-4, 133, 140-165.) Moreover, the "AWP Scheme" alleged in the MCC, in which pharmaceutical companies "marketed the spread" to providers to induce them to prescribe drugs based upon the "profit" generated by receiving reimbursements from Medicare which were higher than their actual costs,[6] has at its very root the

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[6] The AWP MDL court summarized the plaintiffs allegations:

> The pharmaceutical companies vastly overstate the AWPs of many drugs . . . .
>
> This overstatement in the reporting creates a "spread" . . . between the actual cost of a drug to a health care provider, and the reimbursement paid to the provider by the federal government. . . . Defendants actively market this "spread" to providers, who are encouraged to buy drugs from defendants at the highly "discounted" actual prices, and are urged to keep the reimbursement and co-payment spreads for themselves. . . .
>
> For some defendants, the AWP scheme is not the only mechanism used to create the artificial "spreads." Another method involves the provision of "free samples" to health providers who are sometimes encouraged to bill their customers for the samples as they would any

(continued...)

submission of false claims to the government. (See id. ¶¶ 139, 157-165; see also id. ¶ 171 ("Defendant Drug Manufacturers incentivize [*sic*] providers under Medicare Part B to use (and submit reimbursement claims for) the drugs with the highest-inflated AWP. . . ."). The MCC's allegations of kickbacks and other fraudulent inducements made by OBP and its codefendants to providers more than adequately "set government investigators on the trail of fraud." Quinn, 14 F.3d at 655.[7]

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other drug. This "free sample" scheme lowers the providers' overall costs while not reducing the amount they receive in reimbursements from the federal government, or co-payments from consumers, which remain tied to the reported AWPs. Other fraudulent pricing practices include off-invoice pricing, phony consulting fees, as well as debt forgiveness, rebates, and grants. All of these incentives were designed to lower the providers' net cost of purchasing the drugs.

In re Pharm. Indus. Avg. Wholesale Price Litig., 263 F. Supp. 2d 172, 178-79 (D. Mass. 2003). The court issued this opinion in May 2003, nearly six months prior to Duxbury's initial complaint.

[7] The government argues that its prior reports do not constitute public disclosures because they did not contain either the allegation of fraud or both of the essential elements of fraud. (See United States' Statement of Interest in Resp. to Def.'s Mot. to Dismiss Compl. (Docket # 63), 4-6.) Because the MCC constitutes sufficient public disclosure of the alleged fraud, I do not consider whether the government reports also qualify.

### 2. Based Upon

Courts do not uniformly agree about the standard for judging whether an action is "based upon" a public disclosure, and the First Circuit has not yet spoken on the issue. Within the District of Massachusetts, four judges have considered the issue. Three have adopted the "minority rule," which says that an action is "based upon" a public disclosure "only when the allegations supporting the action are 'derived from' the public disclosure." E.g., United States ex rel. Rost v. Pfizer, Inc., 446 F.Supp.2d 6, 19 (D. Mass. 2006) (discussing cases and adopting minority view), vacated on other grounds, Rost, 507 F.3d at 734. One judge has adopted the "majority rule," which states that an action is "based upon" a public disclosure "when the supporting allegations are similar to or the same as those that have been publicly disclosed . . . regardless of where the relator obtained his information." O'Keeffe, 131 F. Supp. 2d at 92 (internal quotation marks, citation and emphasis omitted) (adopting majority view).

I adopt the majority view, which I believe better comports with both the policies underlying the provision and the Supreme Court's recent Rockwell decision. In Rockwell the Court held that the "information" in §§ 3730(e)(4)(A) and (B) is the information underlying the allegations in the relator's action, not the information underlying the

publicly disclosed allegations.[8] 127 S. Ct. at 1407-08. The Court reasoned:

> It is difficult to understand why Congress would care whether a relator knows about the information underlying a publicly disclosed allegation (e.g., what a confidential source told a newspaper reporter about insolid pondcrete) when the relator has direct and independent knowledge of different information supporting the same allegation (e.g., that a defective process would inevitably lead to insolid pondcrete). Not only would that make little sense, it would raise nettlesome procedural problems, placing courts in the position of comparing the relator's information with the often unknowable information on which the public disclosure was based. Where that latter information has not been disclosed (by reason, for example, of a reporter's desire to protect his source), the relator would presumably be out of court. To bar a relator with direct and independent knowledge of information underlying his allegations just because no one can know what information underlies the similar allegations of some other person simply makes no sense.

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[8] As discussed more fully infra, if a qui tam suit is based upon public disclosure, the court lacks jurisdiction unless the relator is an "original source of the information." To be an "original source" the relator must, inter alia, have "direct and independent knowledge of the information on which the allegations are based." 31 U.S.C. §§ 3730(e)(4)(A), (B).

Id. Under the minority view, the Court's exemplar relator – one with "direct and independent knowledge of different information supporting the same allegation" – would not fall into the public disclosure bar at all because his allegations would not be "derived from" the public disclosure. However, the Court's discussion presupposes that a relator's allegation which is similar to or the same as the publicly disclosed allegation is subject to the public disclosure bar and must show that he has direct and independent knowledge of the information underlying his allegations.

In the same vein, other courts have noted that the minority view's narrow reading of "based upon" renders the original source exception superfluous. The minority view, which would not find a qui tam action "based upon" the public disclosure so long as the relator possesses independent knowledge of the allegations, "swallows the original source exception whole." Findley, 105 F.3d at 684; accord United States ex rel. Biddle v. Bd. of Trs. of Leland Stanford, Jr. Univ., 161 F.3d 533, 538 (9th Cir. 1998); United States ex rel. Mistick PBT v. Housing Auth. of the City of Pittsburgh, 186 F.3d at 386-87 (3d Cir. 1999).

Additionally, a broader interpretation of "based upon" is more consistent with the policies underlying the public disclosure bar. O'Keefe, 131 F. Supp. 2d at 93 (minority view "would contravene the congressional policy of prohibiting qui tam actions where the government has sufficient information to pursue the false claim itself" (citing Findley, 105 F.3d at 685)).

As the kickback allegations in the Amended Complaint are the same as those alleged in the MCC, the conclusion is inescapable that Relators' claims are based upon the public disclosures.

### 3. Original Source Exception

Given the public disclosures, Relators may only maintain this action if they qualify as "original sources" for the kickback allegations. 31 U.S.C. § 3730(e)(4)(A). An "original source" is defined as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." Id. § 3730(e)(4)(B).

On this issue, too, the Supreme Court recently provided guidance in Rockwell. The Court first emphasized that the "original source" inquiry is an issue of subject matter jurisdiction. 127 S. Ct. at 1406. It then determined that "the 'information' to which subparagraph [3730(e)(4)](B) speaks is the information upon which the relators' allegations are based," meaning that the inquiry should not focus on whether the relator was the source of the public disclosure, but rather whether he is an original source of the information underlying his own suit. Id. at 1407-08. Finally, the Court held that the term "allegations" in the phrase "information on which the allegations are based" is not limited to the allegations of the original complaint, but "includes (at a minimum) the allegations in the original complaint as amended." Id. at 1408 (emphasis in original).

### a. Duxbury

OBP asserts that Duxbury cannot qualify as an original source because he did not provide the government with his information prior to the public disclosure. Duxbury denies that this is a requirement under the statute. Courts have split on this issue.[9] See Rost, 446 F. Supp. 2d at 22-23 (discussing cases). The plain language of the FCA only requires the relator to provide his information to the government prior to filing his action. See § 3730(e)(4)(B). This unambiguous statutory language must guide the court's interpretation. Lamie v. United States, 540 U.S. 526, 534 (2004); cf. Rost, 507 F.3d at 730 (rejecting an interpretation of the FCA that would "create a new exclusion not articulated in the text"). Accordingly, to be an original source, a relator must: "(1) have independent knowledge of the fraud alleged in his complaint; (2) have direct knowledge of that fraud; and (3) have disclosed this information to the government before filing suit," Rost, 446 F. Supp. 2d at 24, but need not have disclosed the information to the government prior to the public disclosure.

"A relator's knowledge is 'direct' if she acquired it through her own efforts without an intervening agency, and it is 'independent' if her knowledge is not dependent on the public disclosure." O'Keefe, 131 F. Supp. 2d at 93 (citing Quinn, 14 F.3d at 656).

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[9] The Supreme Court did not grapple with this issue in Rockwell, as the relator in that case provided the information to the government prior to the public disclosure. See Rockwell, 127 S. Ct. at 1402.

In his position as a Product Specialist and later Regional Key Account Specialist for OBP's Western Division Oncology sales force, Duxbury was responsible for the promotion and sale of Procrit in the western United States. The complaint alleges that, at defendant's direction, he gave providers free samples of Procrit and instructed the providers to submit Medicare claims for the samples, see, e.g., Am. Compl. ¶¶ 91-93, 99-100, and directly provided discounts, rebates, educational grants, and other "off-invoice" discounts to providers to lower the actual acquisition cost of Procrit, see id. ¶¶ 106-109. His knowledge of the alleged fraud is both independent and direct. Duxbury also alleged in his initial complaint instigating the action that he had provided the information to the government prior to filing the suit. (See Compl. ¶ 9.)

Duxbury therefore qualifies as an original source. However, his direct knowledge of OBP's activities only extends to the time he was employed by the company. He has no direct knowledge of OBP activities occurring after he was terminated in 1998. Therefore, he qualifies as an original source only with regard to allegations concerning the 1992-1998 time period. See Rockwell, 127 S. Ct. at 1409-10.

**b. McClellan**

McClellan does not qualify as an original source. By the express terms of the statute, he would only qualify if he "voluntarily provided the information to the Government before filing an action" based on the information. § 3730(e)(4)(B). Here, McClellan does not assert any new claims of his own, but only "adds additional supporting facts to the legal claims previously made." (Am. Compl. ¶ 28.) He therefore

must show that he provided the information to the government prior to the claims being made, i.e., prior to Duxbury filing suit in November 2003. Although McClellan claims to have "provided such information to the United States before filing suit," Am, Compl. ¶ 16, Relators have proffered no support for this conclusory assertion, and given that Duxbury did not move to add McClellan as a relator until October 2006, the court cannot reasonably infer it. Murphy, 45 F.3d at 522 (party invoking jurisdiction "carries the burden of proving its existence" and "may not rest merely on unsupported conclusions") (internal quotation marks and citations omitted).[10] See also United States ex rel. McBride v. Halliburton Co., Civ. A. No. 05-00828, 2007 WL 1954441, at *3-*4 (D.D.C. July 5, 2007); United States ex rel. Hockett v. Columbia/HCA Healthcare Corp., 498 F. Supp. 2d 25, 51 n.14 (D.D.C. 2007) ("Rockwell[] . . . strongly indicate[s] that each party who wishes to bring a qui tam suit must be able to invoke the court's jurisdiction. To do otherwise would permit the kind of 'claim smuggling' – or in this case, party smuggling – that Rockwell forbids.").[11]

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[10] As discussed supra, the conclusory assertion suffices for Duxbury because it was made in his initial complaint instigating the action. However, there is no indication that McClellan gave his information to the government prior to Duxbury filing suit.

[11] Relators filed an "Offer of Proof' with regard to providing information to the government relating to their third claim for "off-label" marketing. (Docket # 78.) As the Offer consists of a June 2004 letter to the government, it does not support the (continued...)

Even if he qualified as an original source, McClellan would be barred by the "first-to-file" bar. As discussed more fully infra, the first-to-file bar in § 3730(b)(5) prevents private plaintiffs "from bringing related actions based on the same underlying facts." United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1187 (9th Cir. 2001). The first-to-file bar is "exception-free," id., and cannot be circumvented simply by amending the complaint to add McClellan as a relator when his claims would have been barred had they been brought on their own. United States ex rel. Fry v. Guidant Corp., Civ. A. No. 3:03-0842, 2006 WL 1102397, *6 (M.D, Tenn. Apr. 25, 2006); see also Fed. Recovery Servs., Inc. v. United States, 72 F.3d 447, 453 (5th Cir. 1995); LaCorte, 185 F.3d at 191.

**B. Count III: Off-Label Marketing[12]**

OBP argues that both the first-to-file bar and the public disclosure bar preclude this court from exercising jurisdiction over Relators' off-label marketing claim. Because the former does bar the claim, I do not consider the latter.

Section 3730(b)(5)'s "first-to-file" rule provides: "When a person brings an [FCA qui tam] action . . . no person other than the Government may intervene

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assertion that McClellan provided the government with the information prior to November 2003.

[12] "Off-label marking" refers to the promotion of a product for a use not approved by the Food and Drug Administration ("FDA").

or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The first-to-file bar furthers the policy of the FCA in that "[t]he first-filed claim provides the government notice of their essential facts of an alleged fraud, while the first-to-file bar stops repetitive claims." Lujan, 243 F.3d at 1187 (citing LaCorte, 149 F.3d at 232).

Duxbury filed his original complaint in November 2003 ("Duxbury Complaint") (Docket # 1). In December 2003, a separate relator, Kurt Blair ("Blair") filed a qui tam complaint in the District of Colorado which alleged a scheme by OBP to market off-label uses of Procrit. See United States ex rel. Blair v. Ortho Biotech, Inc., Civ. No. 03-02585 (D. Colo. Dec. 22, 2003) ("Blair Complaint") (Docket # 59). The Blair Complaint was unsealed in November 2005, nearly a year before the First Amended Complaint was filed in this action in October 2006. OBP asserts that the Duxbury Complaint did not include the amended complaint's allegations regarding off-label marketing, and those allegations are therefore barred under the first-to-file rule because of the Blair Complaint. Plaintiffs counter that the Duxbury Complaint contained sufficient allegations of off-label marketing by OBP, such that the Blair Complaint was not filed "first" and does not act as a bar to the claim.

**1. Legal Standard**

Although the First Circuit has not yet spoken to this issue, the majority of courts interpret § 3730(b)(5) to bar a later allegation which "states all the essential facts of a previously-filed claim," even if the later claim "incorporates somewhat different

details." LaCorte, 149 F.3d at 232; see also Lujan, 243 F.3d at 1189; Walburn, 431 F.3d at 971; United States ex rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 217-18 (D.C. Cir. 2003). The "common principle is that section 3730(b)(5) precludes a subsequent relator's claim that alleges the defendant engaged in the same type of wrongdoing as that claimed in a prior action even if the allegations cover a different time period or location within a company." Lujan, 243 F.3d at 1188 (internal quotation marks and citation omitted); see also LaCorte, 149 F.3d at 232.

Here, the court must determine which of the complaints – the Duxbury Complaint or the Blair Complaint – was the "first" to assert claims for off-label marketing of Procrit. Stated differently, the court must determine whether the Duxbury Complaint sufficiently alleged an off-label marketing scheme such that the Blair Complaint would be barred by the first-to-file rule. Resolution of this issue requires the court to compare the allegations in the Duxbury and Blair Complaints. See LaCorte, 149 F.3d at 234 n.6 (determining whether later complaint alleges the "same material elements" as claims in the earlier complaint requires "simply [] comparing the original and later complaints"); Merena, 205 F.3d at 102 (same).[13]

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[13] Because neither party raised the issue, I do not address whether the status of the Blair action – i.e., whether the action was "pending" at the time Relators filed their amended complaint – is material to the first-to-file bar in this instance.

### 2. Duxbury Complaint

Relators assert that three paragraphs in the Duxbury Complaint sufficiently alleged an off-label marketing scheme:[14]

> 40. Another method of inflating reimbursement for use of Procrit was through Phase IV Clinical Trials. Phase IV Trials are defined by the FDA as a method of evaluating a drug in a "real world" clinical setting. Ortho Biotech extensively used Phase IV Marketing Trials as a way to accomplish a number of marketing goals:
>
> a) To provide cash payments to a physician, clinic or hospital which lowers the effective net acquisition cost of the drug. This allows the manufacturer to provide a lower "best price" to physicians than what it reports to the Federal Government, resulting in inflated Medicaid payments for the drug.
>
> b) To provide cash payments to a physician, clinic or hospital to influence the physician to use more of the drug in practice.

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[14] These allegations are found under subsection IV.A, "Ortho Commits AWP Fraud to Increase Market Share For Drugs Covered by Medicare Part B," specifically in subsection IV.A.2.d(2), "Phony Drug Studies." (Duxbury Compl. ¶¶ 40-42.)

c) To provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which is inconsistent with its FDA approved indications and administration methods. In 1997, Ortho Biotech launched a massive Phase IV Marketing Trial which paid physicians to dose Procrit at 40,000iu in a once per week dose instead of the FDA approved dosage of 10,000iu three times per week dosage in cancer-chemotherapy patients. The trial was very successful and the once per week dosage is now universally accepted among oncologists. The trial's success also resulted in Medicare Part B paying for 40,000iu/week of Procrit in cancer chemotherapy patients instead of 30,000iu/week - an increase of 33% in payments for each Medicare Beneficiary receiving Procrit for treatment of their chemotherapy related anemia.

41. The approved dosage by the FDA is 10,000iu three times a week. By dosing at 40,000 units once a week, Ortho increases the provider's take, but in doing so, intentionally has established a practice whereby Medicare pays more than the approved FDA dosage. The 40,000iu dosage scheme was successful for Ortho and doctors, but Ortho has not received FDA approval for such dosage. Thousands

of patients have been treated with this dosage. In 1997, Medicare was spending close to $1 billion for EPO.

42. Ortho Biotech's Phase IV Trials also provided thousands of dollars worth of free commercially packaged Procrit to the participating physicians, clinics or hospitals which were billed to Medicare. Again, a simple audit of the account's purchases of Procrit around the time of the trial period and comparison to the amount of Procrit billed to Medicare will identify fraudulent billing practices.

(Duxbury Compl. ¶¶ 40-42) (emphases omitted).

**3. The Blair Complaint**

The Blair Complaint alleged that OBP:

> engaged in a widespread scheme to market and promote to physicians and pharmacists the use of Procrit at dosing levels exceeding what is approved by the FDA. Relator alleges that the activities of Ortho Biotech in marketing Procrit for these non-approved uses were intended to, and did in fact, cause the submission of hundreds of thousands of false claims for reimbursement to the Medicare and Medicaid programs. . . .

(Blair Compl. ¶ 8.) The complaint states that the predominant dosing regimen for Procrit was initially 10,000 units administered three times weekly, for a total of 30,000 units per week. OBP received approval to manufacture a 40,000 unit vial in 1998 or 1999 in order to accommodate an FDA-approved

dosing regimen for an elective surgery indication. The 40,000 unit vials are dosed once per week. In 2000, OBP unsuccessfully sought FDA approval for a 40,000 unit once per week dosing regimen for the drug's oncology indication. (Id. ¶¶ 18-20.) According to Blair, OBP nonetheless embarked on a scheme to market the 40,000 unit vial to physicians for use with oncology patients, because it desired (1) to increase the revenue stream that would result from selling an extra 10,000 units per week; (2) to increase the use of the drug by physicians due to its convenient once per week, instead of thrice per week, dosage; and (3) to compete with another drug expected to obtain FDA approval in the near future which would only require once per week dosage. (Id. ¶¶ 22-26.)

Blair alleged that OBP carried out its scheme through a variety of marketing and incentive programs, including: (1) direct off-label marketing to medical professionals; (2) influencing the results of purportedly independent clinical studies; (3) illegal payments to medical professionals in the form of "educational grants" and "clerkships;" (4) payments to medical professionals for giving presentations on increased dosage of Procrit; or (5) attending consulting conferences sponsored by OBP which pushed increased dosage of Procrit; and (6) rebate programs offered to induce increased prescriptions of Procrit. (Id. ¶ 27.) The complaint describes each of these alleged methods in further detail in over fifty paragraphs. (See id. ¶¶ 28-79.) Blair alleges that the scheme began in 1998. (Id. ¶ 90.)

The complaint refers to a Phase IV trial known as the "Gabrilove study." (Id. ¶¶ 38-43.) It is unclear whether this is the same Phase IV trial referenced in

the Duxbury Complaint. The Gabrilove study concluded that, for the oncology indication, once weekly dosing at 40,000 units was as effective as three times weekly dosing at 10,000 units per dose. Blair alleged that the study was improperly influenced by OBP's selection of participating physicians and patients. Blair further alleged that OBP used the study to financially reward physicians for proscribing Procrit at higher doses.

Blair's FCA claim was based upon health providers' improper claims for Medicare and Medicaid reimbursement of the 40,000 unit prescription, which was not eligible for reimbursement. "But for Ortho's promotion of off-label uses, most of the ineligible claims for payment of Procrit prescriptions would never have been filed. Every off-label Procrit prescription caused by Ortho Biotech's off-label promotion of Procrit is a false claim caused by Ortho Biotech for the purposes of the [FCA]." (Blair Complaint ¶ 83; see also id. ¶ 88.)

**4. Discussion**

A superficial comparison of the allegations in the two complaints suggests they are similar. Both allege that oncology providers are improperly dosing Procrit at 40,000iu once per week instead of the FDA-approved dosage of 10,000iu three times a week, resulting in higher reimbursement payments by Medicare and Medicaid. However, similar allegations about the behavior of providers are unimportant; it is OBP's behavior which is relevant in this instance. Providers may lawfully prescribe a

drug for an off-label use; the sine qua non of manufacturer liability is the promotion of the unapproved use.[15] Viewed through this lens, the differences between the Duxbury and Blair Complaints become apparent.

Although the Duxbury Complaint alleged that OBP paid physicians to participate in clinical trials and used Phase IV trials "[t]o provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which is inconsistent with its FDA approved indications and administration methods," (Duxbury Compl. ¶ 40(c)), this allegation does not provide the essential facts regarding a widespread scheme to promote off-label uses of Procrit. To the contrary, the complaint alleges that one trial in 1997, and not any other OBP activities or initiatives, led physicians to switch to the higher dosage of Procrit. This bare bones allegation cannot act as a placeholder for the widespread off-label marketing scheme that Relators now wish to allege.[16]

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[15] See Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer: Hearing Before the House Oversight and Government Reform Committee, 110th Cong. 6-7 (Feb. 9, 2007) (statement of Lewis Morris, Chief Counsel, Office of Inspector General, Department of Health and Human Services) ("While physicians may lawfully prescribe a drug for an off-label use, manufacturers are prohibited from promoting a drug for uses other than FDA-approved uses.").

[16] The Amended Complaint alleges an "inflated dosing scheme" which consisted of (1) promoting off-label dosing of Procrit; (2) promoting the higher-dose of Procrit for an oncology indication even though it was only approved for a surgery (continued...)

See Lujan, 243 F.3d at 1187.[17] The first-to-file rule accordingly would not operate to bar the Blair Complaint's allegations of an off-label marketing scheme. However, as the "first" complaint to allege claims based upon OBP's alleged off-label marketing of Procrit, the Blair Complaint bars Relators' off-label marketing claims. See Grynberg v. Kock Gateway Pipeline Co., 390 F.3d 1276, 1279 (10th Cir. 2004). Count III is therefore dismissed.

## IV. Rule 9(b)

Defendant next challenges Relators' claims as deficient under Rule 9(b), which requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R Civ. P. 9(b). Rule 9(b) applies to FCA claims and "requires relators to 'provide details that identify particular false claims for

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indication; (3) paying kickbacks to induce use of Procrit; (4) using "sham drug trials" to falsify eligibility for Medicare reimbursement of a higher dose of Procrit; and (5) changing the vial size in which free Procrit was distributed. (Am. Compl. ¶ 132.)

[17] Indeed, correspondence between the plaintiff and the government suggests that the Duxbury Complaint failed to put the government on notice of OBP's alleged off-label marketing scheme. (See June 18, 2004 Letter (Docket # 78), 6 ("We believe the following paragraph describes a more important and damaging fraud identified in Mr. Duxbury's complaint, which we described (see Complaint ¶¶ 40-42) but are not sure you have grasped based on your letter and the interview of Mr. Duxbury.").)

payment that were submitted to the government.'" Rost, 507 F.3d at 731 (quoting United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004)). Because the court only has jurisdiction over Duxbury's allegations of kickbacks occurring from 1992 to 1998 (see supra Section III.A.3.a), I will only evaluate those claims for sufficiency under Rule 9(b).

FCA liability attaches only to false claims, not to any underlying fraudulent activity or to the government's wrongful payment. "Evidence of an actual false claim is the sine qua non of a False Claims Act violation." Karvelas, 360 F.3d at 225 (internal quotation marks and citation omitted). The Amended Complaint alleges particularized details about OBP's underlying scheme to induce doctors to prescribe Procrit by granting them a variety of kickbacks, including rebates and other off-invoice discounts, educational grants, and the like. (See, e.g., Am. Compl. ¶ 211 (identifying particular amounts of money or percentages of discounts given to particular providers).) However, it is not enough to allege details of the scheme if there are not also particularized allegations regarding the false claims that were actually submitted to the federal government. As the First Circuit stated in Karvelas, a case in which a relator alleged that a health care provider submitted false Medicare and Medicaid claims to the federal government,

> Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the 'circumstances constituting fraud or mistake' that must be pled with particularity pursuant to Rule 9(b). However, such pleadings

> invariably are inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action. As applied to the FCA, Rule 9(b)'s requirement that averments of fraud be stated with particularity . . . means that a relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in the complaint. However, . . . we believe that some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

Id. at 232-33 (footnotes and internal quotation marks and citation omitted).

Karvelas suggests that Rule 9(b) may be satisfied if the complaint as a whole is sufficiently particular to pass muster under the FCA, although some questions remain unanswered. Karvelas, 360 F.3d at

233 n.17. Nonetheless, even giving Duxbury the "benefit of such flexibility," Rost, 507 F.3d at 732, the allegations are inadequate because they are indistinguishable from those found insufficient in Karvelas. In Karvelas, the relator, a former employee of the defendant health care provider, filed a 93-page complaint which alleged sixteen complex schemes of fraud "at considerable length." Karvelas, 360 F.3d at 232-33. However, the complaint "never specifie[d] the dates or content of any particular false or fraudulent claim allegedly submitted for reimbursement by Medicare or Medicaid," and "did not set forth the specifics . . . of any one single cost report, or bill, or piece of paper that was sent to the Government to obtain funding." Id. at 233. Although the relator alleged serious violations of federal regulations, his allegations were insufficient to support a claim under the FCA because he "fail[ed] to identify with particularity any actual false claims that the defendants submitted to the government." Id. at 235.

The same is true here. Although Duxbury identifies providers and approximate amounts of free samples, discounts, "off-invoice" rebates, or educational grants, he fails to identify a single false claim consequently filed by these providers. (See, e.g., Am. Compl. ¶ 211.) In the closest case, Duxbury alleges that St. Joseph's Hospital in Tacoma, Washington, was given "off-invoice" rebates of 14% for the purchase of Procrit, and submitted "approximately 4,800 claims a month for Medicare reimbursement." (Id. ¶ 211(a).) However, this allegation fails to provide even one (much less "some") of the specifics required by Karvelas for "at least some of the claims," viz., the "dates of the

claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices . . . ." 360 F.3d at 232-33.

Duxbury argues that he cannot identify all the false claims submitted to the government because the claims "were submitted by Providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator's control." (Am. Compl. ¶ 232.) Yet, this is precisely the point of requiring relators to identify particular claims, for under Karvelas and Rost the court is not permitted to surmise that false claims "must have" occurred as a result of defendant's conduct. "No matter how likely the existence of false claims, this court cannot speculate that such claims inevitably flowed from Defendants' activities." Rost, 446 F. Supp. 2d at 28 (citing Karvelas, 360 F.3d at 235).

Similarly, although Duxbury alleges that providers submitted HCFA Forms 1500 and 2552 and other certifications of compliance with the anti-kickback statute in order to get false claims paid (see Am. Compl. ¶¶ 230, 234-37), the mere identification of the template forms which providers used to submit reimbursement in the abstract is insufficient when not tied to a particular claim filed by a particular provider. Karvelas, 360 F.3d at 231 n.13 (Rule 9(b) standard applies to documents that are "regularly-

filed," i.e., relator is not absolved of the requirement to plead particulars simply because the document is one routinely filed with the government).[18]

## V. Conclusion

Although the court has subject matter jurisdiction to hear Duxbury's claims of alleged kickbacks which occurred during his employment at OBP, his allegations lack the particularity required under Rule 9(b) and this Circuit's precedent. This complaint was initially filed in 2003 and unsealed in 2005, and it is now 2008. Relators have already amended their complaint once as of right, and the court is not inclined to allow further amendments.

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[18] Duxbury alleges that the kickbacks violated 31 U.S.C. §§ 3729(a)(1) and (2). Section 3729(a)(1) imposes liability upon a person who "knowingly presents, or causes to be presented . . . a false or fraudulent claim for payment or approval" to the United States Government. Section 3729(a)(2) imposes liability upon a person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." Neither party suggests that the particularity requirements should be analyzed separately for the two subsections, and the court does not deem it necessary, as its analysis applies equally to both subsections. See Rost, 507 F.3d at 733 (rejecting assertion that subsections must be analyzed separately). Duxbury also includes a puzzling reference to stating a claim under § 3732(b), which provides federal court jurisdiction for state law claims based upon FCA violations. (See Am. Compl. Count I, at 58.) As the complaint does not allege violations of any specific state law (in Duxbury's sales region in the western United States or otherwise), § 3732(b) is inapplicable.

Accordingly, defendant's motion to dismiss the amended complaint with prejudice (Docket # 56) is ALLOWED.[19]

Judgment may be entered for defendant.

January 28, 2008
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES
DISTRICT JUDGE

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[19] As the government has not intervened, the court does not dismiss this action with prejudice as to the United States. See United States ex rel. Williams v. Bell Helicopter Textron Inc., 417 F.3d 450, 455 (5th Cir. 2005) (improper to dismiss FCA claims with prejudice as to United States when government did not intervene in qui tam action which was deficient under Rule 9(b)).

## APPENDIX C

**United States Court of Appeals**
**For the First Circuit**

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No. 08-1409

UNITED STATES, ex rel. Mark Eugene Duxbury and Dean McClellan

Plaintiff

MARK EUGENE DUXBURY; DEAN MCCLELLAN

Plaintiffs - Appellants

v.

ORTHO BIOTECH PRODUCTS, LP

Defendant - Appellee

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Before

Lynch*, Chief Judge,
Torruella, Siler**, Boudin*,
Lipez and Howard, Circuit Judges.

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ORDER OF COURT

Entered: September 4, 2009

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* Chief Judge Lynch and Judge Boudin are recused and did not participate in the consideration of this matter

** of the Sixth Circuit, sitting by designation

Pursuant to First Circuit Internal Operating Procedure X(C), the petition for rehearing en banc has also been treated as a petition for rehearing before the original panel. The petition for rehearing having been denied by the panel of judges who decided the case and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc, it is ordered that the petition for rehearing and petition for rehearing en banc be denied.

By the Court:

/s/Richard Cushing Donovan, Clerk

cc:
Jan Richard Schlichtmann
Kathleen C. Chavez
Robert M. Foote
Paul E. Simmerly
Sara M. Bloom
Patricia M. Connolly
Douglas N. Letter
Charles W. Scarborough
Jaime Ann Yavelberg
Susan L. Burke
Geoffrey E. Hobart
Ethan M. Posner
Rebecca Rohr
Clevland Lawrence, III

## APPENDIX D

## UNITED STATES DISTRICT COURT
## FOR THE DISTRICT OF MASSACHUSETTS

| | |
|---|---|
| UNITED STATES OF AMERICA, *ex rel.* MARK EUGENE DUXBURY and DEAN McCLELLAN<br><br>Relators,<br><br>v.<br><br>ORTHO BIOTECH PRODUCTS, L.P.,<br><br>Defendant. | CIVIL ACTION: 03-CV-12189-RWZ<br><br>**(LEAVE TO FILE AMENDED COMPLAINT GRANTED 10-24-06)** |

**FIRST AMENDED COMPLAINT**

**AND**

**DEMAND FOR JURY TRIAL**

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## VI. FACTUAL BACKGROUND

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### C. Defendant's Illegal Conduct.

#### C(1). Defendant's Scheme to Increase the Spread Between AWP and the Effective Cost of Procrit

. . . .

##### b. Defendant's Kickbacks to Increase the Spread Between AWP and the Effective Cost of Procrit

###### (1) Free Drug

91. Defendant, through Relators and other sales personnel and marketing representatives, also provided free commercially packaged and labeled drugs to Providers as a means of lowering actual acquisition cost of Procrit to Providers. The free drugs were used to offset the total cost associated with the purchases of the drugs, thereby increasing the "spread" between actual acquisition cost and Medicare reimbursement rates based on AWP.

92. Defendant specifically told Providers to bill patients for the free Procrit, which Defendant knew was unlawful.

93. Both Relators have personal knowledge that Defendant commonly directed its sales representatives to provide free Procrit to Providers

and instruct the Providers to submit claims for Medicare reimbursement for said Procrit.

94. Free product is not used by Defendant in calculating or reporting the AWP despite the fact that the substantial quantities of free drug given to Providers effectively lowered net acquisition cost. The failure to include free drugs in calculating the AWP, contributed to the inflated AWP.

95. Although Defendant provided free product and marketed free Procrit as a way to lower the Providers' actual cost of Procrit. Defendant did not include the value of the free product in calculating the AWP for Procrit. Thus, Defendant effectively and improperly passed on the cost of the free product directly to Medicare.

96. The free Procrit provided to Providers by Defendant's sales representatives, including but not limited to Relators, were drug samples within the meaning of 21 U.S.C. § 353(c)(1). Defendant provided the free Procrit with the illegal intent that Provider's submit claims for reimbursement to Medicare for said free drug.

97. Defendant offered substantial quantities of free Procrit through "Patient Trial Cards." These are sequentially numbered documents that identify the Provider who received the drug and the representative who provided the drug. There were thousands of "Patient Trial Cards" provided to sales representatives, each of which was worth well over one thousand dollars ($1,000) in free Procrit. For example, Relator McClellan had over 400 Patient Trial Cards in his possession at one time. Medicare was billed for free Procrit and the free Procrit was not accounted or in calculating AWPs. Relator

McClellan has copies of hundreds of "Patient Trial Cards" that he gave directly to Providers with the intent that the Providers would submit claims for reimbursement to Medicare for the free Procrit.

98. Relators have direct and independent knowledge that Defendant gave free samples of Procrit to Providers to induce them to use Procrit and lower the actual cost of the drug.

99. Both Relators, at the direction of and as agents of Defendant, personally and directly gave free Procrit to Providers and told providers to submit claims for reimbursement to Medicare for the free Procrit.

100. Defendant routinely referred to free Procrit as "cash." Defendant employees Thomas Amick, William Pearson, Robert Ashe, George Mooney, William Ball, John Woodhouse, Keith Wood, Michael Barton and Robert Nelson instructed Relator Duxbury to treat free Procrit as a "cash" equivalent incentive to Providers.

101. Defendant employees which include numerous managers during this time period, including but not limited to Dwayne Marlowe, James Scelfo, Robert Ashe instructed Relator McClellan to treat free Procrit as a "cash" equivalent incentive to Providers.

102. For example, in or about February 2001, one of Defendant's product specialists reported to Defendant's regional manager, Dwayne Marlowe, in a Status Report that an oncology clinic within his territory had failed to obtain reimbursement for approximately $8,500 worth of Procrit. Marlowe instructed the product specialist to provide free Procrit to the account equal in value to the clinic's

reimbursement losses. Marlowe instructed the product specialist to submit to Defendant Patient Trial Cards on the clinic's behalf, to get it free Procrit. The product specialist would have a doctor sign numerous cards at a time so as not to draw attention, and then every two weeks he would submit just a few of them to Defendant for fulfillment. These allegations are supported by contemporaneously generated documents in the possession of Relator McClellan.

103. Both Relators have direct and independent knowledge of Defendant's unlawful practices, promotional and marketing policies, and illegal schemes related to the provision of free Procrit to Providers with the direction to Providers to submit claims for reimbursement to Medicare.

**(2) Discounts and Rebates**

104. Defendant offers Providers discounts and rebates for Procrit purchases to induce them to buy Procrit.

105. Both Relators have direct and independent knowledge that Ortho provided discounts, rebates, and other financial inducements to stimulate the sale of Procrit and lower the actual cost of purchasing Procrit.

106. Both Relators possess documents showing that as a sales representative of Defendant they provided discounts, rebates, and educational grants directly to Providers purchasing Procrit.

107. Both Relators, at the direction of and in agency for Defendant, gave Providers "off-invoice" hidden discounts, grants, rebates and other

incentives to lower the actual acquisition cost of Procrit.

108. Relator Duxbury also possesses documentation of rebates given in 1993 by Defendant to the Mid-Columbia Kidney Center, for purchases of Procrit. Again, Relator Duxbury has independent and direct knowledge of the provision of the rebate to Mid-Columbia Kidney Center, because Defendant directed Relator Duxbury to provide the off-invoice rebate. Defendant represented to Relator Duxbury that the rebate was provided "off-invoice" for the exclusive purpose of inducing more Procrit purchases by lowering the actual acquisition cost and increasing the kidney center's profit to be made by the AWP spread at the expense of Medicare.

109. Both Relators possesses first hand direct and independent knowledge that Defendant's purpose of giving cash payments to physicians to serve on Advisory Boards was to influence them to prescribe and advocate the prescription of Procrit. Both Relators were told by Defendant that the purpose was to influence the providers to prescribe Procrit. Both Relators were also given a February 26, 1997 memorandum, to Hematopoietic Product Specialists, from Defendant's manager William Pearson re: Advisory Board Member Interaction, that set forth in writing the unlawful intent to provide cash payments as an inducement to physicians to prescribe Procrit.

110. As of August 13, 2003, Defendant guaranteed physicians a discount of 6% (and potentially up to 10%) off the list price if they purchased Procrit.

111. In an April 13, 2004 internal training presentation, Defendant's Executive Director of Contracting and Government Contracts Tom Hiriak described Defendant's discount and rebate program for physicians. He explained that physicians can purchase Procrit off several discount programs" that "provide a 5% off-invoice (upfront) discount." However, this discount is not provided directly by Defendant. Rather, through a "chargeback" process the drug distributor provides the discount and "'charges back' to collect the 5% discount."

112. Rebates of 5% were normal until approximately 2002, when Amgen released Aranesp. Until then, Procrit was 17% cheaper than Amgen's competing product, Epogen.

113. Since the introduction of Aranesp, Defendant has marketed an aggressive rebate program.

114. A copy of a 2003 promotion piece for physicians refers to rebates "paid in product."

115. The Hiriak internal training presentation states that Ortho Biotech rolled out two physician rebate programs in January 2004. As of that date, physicians could qualify for rebates of between 15.5% and 20% off the discounted price, depending on their purchase volume.

116. Several additional rebate percentage points were authorized in March 2004.

117. Hospitals receive reimbursement under an "APC" code. As of early 2004, they received 73.4 percent of AWP. Because the reimbursement is based in part on AWP, Defendant did "market the

spread" between the actual sales price to hospitals and AWP.

118. In 2003, Defendant had a rebate program offering hospitals an 8% rebate.

119. Defendant's executives trained sales representatives on calculating the Medicare reimbursement for Procrit at annual sales meetings. Combined with the promotional materials described above, sales representatives were equipped to calculate the spread between a customer's net cost and the Medicare reimbursement.

**(3) Unrestricted Educational Grants**

120. Defendant maintained large pools of money to be disbursed as unrestricted educational grants in what was called "business development grants" later renamed the S.A.F.E. program. Each unrestricted educational grant required a written request from the sales representative to his/her manager and included a description of what benefit to Defendant is expected in return for the grant. Defendant used these grants as "kickbacks" to buy influence with physicians and hospitals. These "kickbacks" were directly tied to the Providers' purchase of Procrit.

121. One example of this type of "kickback" given to Providers to purchase Procrit is Relator Duxbury possesses documentation of a ten thousand dollar ($10,000) and twenty thousand dollar ($20,000) unrestricted grants that Defendant gave St. Joseph's Hospital in Tacoma, Washington in 1992 and 1993 conditioned upon the purchase of Procrit. The grants were given in connection with and in consideration for continued purchase of Procrit, and

was used as a way to lower the actual acquisition cost of Procrit to the Provider.

122. In order to convert a hospital with a large dialysis center to Procrit, Defendant provided unrestricted educational grants totaling $30,000 during an 18-month period beginning in the spring of 1993. The account was St. Joseph's Hospital in Tacoma, Washington. The grants substantially reduced the effective net acquisition price (which was already 15% below AWP) for Procrit and were not used by Defendant in reporting its AWP.

123. In 2002, a site of U.S. Oncology, a nationwide oncology practice, within the district of Defendant's manager James Scelfo, was given an annual grant of $50,000 to support a "Life Beyond Cancer" educational program. In 2003, however, after Defendant lost U.S. Oncology's contract to provide it with Procrit, Defendant reduced its funding to $10,000.

**(4) Membership on Advisory Boards**

124. Pharmaceutical companies established Advisory Boards to allow the drug manufacturer to bring medical experts to a central location where they can hear presentations on the manufacturer's products, new research areas and information regarding off-label use. The Advisory Board members are expected to provide feedback to the manufacturer on the quality of the information they heard, evaluate the relative importance of clinical data they were presented, and reinforce existing research directions or suggest new ones.

125. Defendant used Advisory Boards not to gather new research ideas, but to give cash and benefits to oncologists to promote sales of its drug.

126. In a memorandum to Defendant's Procrit sales force dated February 26, 1997, National Field Sales Manager Bill Pearson explained the purpose of Ortho Biotech's Advisory Boards: "One of the operating strategies for our Integrated Business Plan is to ***develop thought leader endorsement to establish PROCRIT as standard of care***. Our Clinical Affairs Department has been very active in developing tumor specific, HIV, and fatigue advisory boards to develop thought leader endorsement and establish PROCRIT as the standard of care in treating anemic cancer patients."

127. Defendant used Advisory Boards to make cash payments to influential physicians and take them to meetings at resorts in order to gain influence among leaders in the oncology community. At these meetings, minimal time was spent discussing information of medical value.

**(5) Phony Drug Studies**

128. Another method of inflating reimbursement for use of Procrit was through phony drug studies. Phase IV clinical trials are defined by the FDA as a method of evaluating a drug in a "real world" clinical setting. Defendant extensively used a Phase IV marketing trial as a way to accomplish a number of marketing goals:

a) To provide cash payments to a physician, clinic or hospital which lowered the effective net acquisition cost of the drug. This allowed the manufacturer to provide a

lower "best price" to physicians than what it reported to Federal or State Governments, resulting in inflated Medicare and Medicaid payments for the drug;

b) To provide cash payments to a physician, clinic or hospital to influence the physician to use more of the drug in practice.

c) To provide cash payments in order to encourage the physician, clinic or hospital to use the drug in a way which was higher than the FDA-approved dosage. In 1997, Defendant launched a massive Phase IV marketing trial to increase the dosage – and Government reimbursement – by 33% for each Medicare Beneficiary receiving Procrit for Other Hidden and Improper Inducements and Price Reductions

**(6) Other Hidden and Improper Inducements and Price Reductions**

129. Defendant has provided and/or arranged for many other non-public financial inducements to stimulate sales of Procrit at the expense of Medicare and Medicaid. Such inducements included volume discounts, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and educational and promotional grants. All of these incentives were designed to lower the providers' net cost of purchasing Procrit. And again, the value of these services was kept "off the book," so as to not be reflected in the AWP, which in turn inflated the AWP.

130. During the time of both Relators' employment, Defendant offered substantial discounts, rebates, unrestricted educational grants, and free commercially packaged Procrit to Providers in order to create a lower effective net purchase price and a greater profit spread from the inflated AWP reported to Medispan, *Red Book*, and other publishers. Defendant used surrogate companies like Charise Charles, Lt. and MarketCheck, Inc., to facilitate these schemes. The surrogate companies would use the U.S. mail to send rebates to Providers throughout the country. These rebates were hidden from Medicare and were not accounted for in calculating Defendant's reported AWP for Procrit.

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**D. Defendant's Illegal Conduct Caused False Claims to be Submitted to Medicare**

**D(1). RELATOR DUXBURY'S ACCOUNTS:**

211. From 1992 through 1998, Relator Duxbury sold over 13 million dollars worth of Procrit on behalf of the defendant. Relator Duxbury has specific knowledge that approximately 80 percent of the Procrit sales that he generated were submitted by his accounts as false or fraudulent claims for Medicare reimbursement. This knowledge is based on his personal knowledge, observation and direct communications with the accounts he developed and maintained during his employment and is supported by the documents contemporaneously generated by Relator Duxbury and defendant during the term of his employment.

The following accounts submitted false and fraudulent claims for Medicare reimbursement:

a. St. Joseph's Hospital in Tacoma, Washington purchased approximately 1.7 million to 2 million dollars a year of Procrit from Defendant during the period between approximately 1993 through 1997, which was submitted to and reimbursed by Medicare. The Procrit was administered for the treatment of patients with dialysis related anemia. During this period St. Joseph's submitted approximately 4,800 claims a month for Medicare reimbursement. St. Joseph's was provided so-called "unrestricted educational grants" by the Defendant totaling more than $30,000, which Defendant intended to be and was in fact not a "grant" but a "kickback" for St. Joseph's purchase of Procrit. These "kickbacks" were paid out of Defendant's "Regional Business Development" pool which was a "slush fund" to induce the purchase of Procrit by accounts. Defendant intentionally failed to report these payments to the US Government in order to keep secret the profit spread between the rate upon which Medicare reimbursed medical providers like St. Joseph's for Procrit. St. Joseph's contract with Defendant provided St. Joseph's with an "off-invoice" rebate of 14% for the purchase of Procrit. Defendant intentionally failed to report these "off-invoice" rebates to the US Government in order to keep the Medicare reimbursement rate to Providers like St. Joseph's at artificially inflated levels so that the Providers could benefit from the profit-spread between the Provider's actual acquisition cost and the Medicare reimbursement rate. Defendant actively marketed Procrit to St. Joseph's by representing to St. Joseph's that it could profit on the

administering of Procrit by exploiting the profit spread so that St. Joseph's could "turn the dialysis unit into a profit center". As a result of Defendant's actions, Defendant knowingly caused the presentation by St. Joseph's of these false and fraudulent claims to the United States Government.

b. In 1998 Rainier Oncology of Puyallup, Washington was provided more than $20,000 of free commercially packaged Procrit from Defendant under the direction of John Woodhouse (Seattle District Manager) under the guise of running an unlawful mini-trial so that Rainier Oncology could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to Rainer Oncology in order to induce the provider to administer Procrit at the "off-label" dosage of 40,000 IU 1X/week. As a result, Defendant knowingly caused the presentation by Rainier Oncology of these false claims to the United States Government.

c. In 1993 Memorial Clinic in Olympia, Washington was provided approximately $15,000 of free commercially packaged Procrit from Defendant under the direction of Robert Nelson (Seattle District Manager) so that Memorial Clinic could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to Memorial Clinic in order to induce the provider to purchase Procrit. Memorial Clinic was reimbursed by Medicare for the free commercially packaged Procrit. In 1993-98

Defendant induced Memorial Clinic to use the fraudulently obtained Medicare reimbursement to purchase additional Procrit by giving Memorial Clinic "off-invoice" rebates of 5-8% so that Memorial Clinic would receive Medicare reimbursement which was significantly more than what they actually paid for the product. As a result, Defendant knowingly caused the presentation by Memorial Clinic of these false claims to The United States Government.

d. In 1997-98 Western Washington Cancer Treatment Center in Olympia, Washington received more than $5,000 of free commercially packaged Procrit from Defendant under the direction of Robert Ashe so that Western Washington could submit the free product for reimbursement to Medicare under the false and fraudulent certification that the provider had paid for the product. Defendant intended the free commercially packaged Procrit to be a "cash equivalent" "kickback" to Western Washington in order to induce the provider to purchase Procrit and to administer Procrit at the "off-label" once a week dosing regimen. Western Washington was reimbursed by Medicare for the free commercially packaged Procrit. As a result, Defendant knowingly caused the presentation by Western Washington of these false claims to The United States Government.

e. In 1993, the Mid Columbia Kidney Center in Kennewick, Washington under the direction of Dr. John Boykin, submitted claims to Medicare and was subsequently reimbursed by Medicare approximately $75,000 for the administering of Procrit to Mid Columbia Kidney Center's patients. Mid Columbia Kidney Center's agreement with Defendant provided Mid Columbia Kidney Center with an "off-invoice"

rebate of 5-8% for the purchase of Procrit. Defendant intentionally failed to report these "off-invoice" rebates in order to keep secret the "profit spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread. Defendant actively marketed Procrit to Mid Columbia Kidney Center by representing that Mid Columbia Kidney Center could profit on the administering of Procrit by exploiting the "profit-spread" between the actual acquisition cost and the Medicare reimbursement rate. As a result of Defendant's actions, Defendant knowingly caused the presentation by Mid Columbia Kidney Center of these false and fraudulent claims to The United States Government.

f. In 1994-1996, St. Peter's Hospital in Olympia, WA, submitted claims to Medicare and was subsequently reimbursed by Medicare for approximately two million dollars of Procrit. St. Peter's contract with Defendant provided St. Peter's with an "off-invoice" rebate of 14% for the purchase of Procrit. Defendant intentionally failed to report to the US Government these "off-invoice" rebates in order to keep secret the "profit spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread. Defendant actively marketed Procrit to St. Peter's by representing to St. Peter's that it could profit on the administering of Procrit by exploiting the "profit-spread". As a result of Defendant's actions, Defendant knowingly caused the presentation by St. Peter of these false and fraudulent claims to The United States Government.

g. In 1994-1997 Memorial Clinic Oncology Group in Washington purchased about approximately

$750,000 of Procrit. Memorial Clinic Oncology Group's agreement with Defendant provided Memorial Clinic Oncology Group with an "off-invoice" rebate of 5% for the purchase of Procrit. Defendant intentionally failed to report to the US Government the "off-invoice" rebates in order to keep the "profit spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate so that the Providers could benefit from the spread. Defendant actively marketed Procrit to Memorial Clinic Oncology Group by representing to Memorial Clinic Oncology Group that it could profit on the administering of Procrit by exploiting the "profit-spread". In 1998 Memorial Clinic's Oncology Department participated in a sham "Phase IV" trial through which they received more than $32,000 of free drug that was intended to be submitted for Medicare reimbursement as if the Provider had paid for the drug. Approximately sixty percent of Procrit administered by Memorial Clinic Oncology Group was submitted and reimbursed by Medicare. As a result of Defendant's actions, Defendant knowingly caused the presentation of Memorial Clinic Oncology Group's false and fraudulent claims to the United States Government. Memorial Clinic Oncology Group also received approximately $50,000 in free commercially packaged Procrit from the Defendant, so that Memorial Clinic Oncology Group could submit the free Procrit to and be reimbursed by Medicare. Memorial Clinic Oncology Group was reimbursed by Medicare for the free commercially packaged Procrit. As a result, Defendant knowingly caused the presentation by Memorial Clinic Oncology Group of these false and fraudulent claims to The United States Government.

h. In 1996 Swedish Hospital in Seattle, Washington under the direction of Defendant's Regional Business Director, George Mooney and Manager Hilton Dempsey was given cash in the form of a so-called "unrestricted educational grant" in the amount of approximately $15,000. In actuality the payment was a monetary inducement or "kickback" to induce the provider to purchase Procrit. Provider subsequently purchased over $100,000 of Procrit of which approximately 50% was submitted for Medicare reimbursement. Defendant intentionally failed to report to the US Government the cash payment made to Swedish Hospital in order secret the "profit-spread" between the actual acquisition cost to the Provider and the Medicare reimbursement rate. As a result, Defendant knowingly caused the presentation by Swedish Hospital of these false and fraudulent claims to The United States Government.

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## VIII. COUNTS

### COUNT I

### KICKBACKS IN VIOLATION OF THE FALSE CLAIMS ACT
### (31 U.S.C. §§ 3729(a)(1), (a)(2), and 3732(b))

226. Relators reallege and incorporate by reference the preceding allegations.

227. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-32, as amended.

228. Defendant gave kickbacks to providers and hospitals to induce them to prescribe Procrit. These kickbacks included free Procrit, off-invoice discounts and cash in the form of rebates, consulting fees, educational grants, payments to participate in studies or trials, and advisory board honoraria.

229. Defendant's kickbacks caused providers and hospitals to submit false claims for payment to Medicare for Procrit. In addition, by giving off-invoice discounts to Providers and hospitals that resulted in actual invoices to be false, Defendant used a false record or statement to get a false claim paid by the Government.

230. Defendant caused Providers to submit/use the HCFA Form 1500, and other such forms as a false statement/record to get a false claim paid.

231. Defendant published a false AWP in the pharmaceutical compendia, thus using a false record/statement to get a false claim paid by the government.

232. Relator cannot identify at this time all of the false claims caused by Defendant. The false claims were submitted by Providers with most of whom Relator has had no dealings, and the records of the false claims are not within Relator's control. Specification of the vast number of false claims would be burdensome to the Court and the parties. The time period of the false claims was from December 1992 to the present. Such claims were made across the United States.

233. In submitting these claims for payment, providers and hospitals expressly or impliedly certified that they complied with the anti-kickback statute.

234. This certification included the Certification Statement in the Medicare Health Care Provider/Supplier Application, OMB Approval No. 0938-0685. This Certification Statement reads in part: "I understand that payment of a claim by Medicare or other federal health care programs is conditioned on the claim and the underlying transaction complying with such laws, regulations and program instructions (including the anti-kickback statute and the Stark law) . . . ."

235. In addition, hospital cost reports (Form HCFA-2552) provide:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified by this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines, and/or imprisonment may result.

236. The form also requires the following certification by an officer or administrator of the health care provider:

> I hereby certify that I have read the above statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by . . . (Provider Name(s) and Number(s)) for the cost reporting period beginning . . . and ending . . . and that to the

> best of my knowledge and belief it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.

237. In addition, on hospitals' cost reports, they certify that the reports are "true, correct, and complete" and "prepared . . . in accordance with applicable instructions, except as noted."

238. Because Defendant had provided the providers and hospitals kickbacks to induce them to use Procrit, all these certifications were false.

239. Defendant's kickbacks were a substantial factor causing the submission of the false claims for payment for Procrit. Defendant used kickbacks to induce providers and hospitals to use Procrit to treat dialysis patients and to submit reimbursement claims for such prescriptions. In the absence of these kickbacks, the providers and hospitals would not have purchased Procrit. In addition, Defendant used kickbacks to convince providers and hospitals to prescribe 40,000 units of Procrit 1X/per week to oncology patients and to submit corresponding reimbursement claims, and in the absence of the kickbacks providers and hospitals would have prescribed 30,000 units in 10,000 IU 3X/week of Procrit or the Providers would have used another alternative product or therapy.

240. Providers' and hospitals' submission of false claims for payment to Medicare, were a foreseeable result of Defendant's kickbacks. Further, not only were they foreseeable but they were the intended consequence of the kickbacks.

241. Defendant's kickbacks would have been material to the Government's decision to pay the reimbursement claims for Procrit. Compliance with the anti-kickback statute is central to the reimbursement plan of Medicare. If the Government had known that the reimbursement claims were induced by Defendant's kickbacks, it would not have paid them.

242. Through the acts described above, Defendant and its agents and employees knowingly caused to be presented to the United States government false and fraudulent claims, records, and statements in order to obtain reimbursement for health care services provided under Medicare.

243. Providers' false and fraudulent claims were submitted for reimbursement based on AWP to Medicare on a HCFA 1500.

244. These claims for payment were false because (i) they were not for a use eligible for reimbursement under the Medicare Act, (ii) they did not disclose the illegal scheme that induced the claims for reimbursement at inflated doses, (iii) were seeking reimbursement based on a false and inflated AWP; (iv) were for reimbursement of Procrit that Defendant gave to at no cost, and/or (iv) they were induced by illegal kickbacks and other monetary incentives.

245. Through the acts described above and otherwise, Defendant and its agents and employees

knowingly made, used, and/or caused to be made or used false records and statements in order to get such false and fraudulent claims paid and approved by the United States government.

246. The United States and its fiscal intermediaries/carriers, unaware of the falsity of the records, statements, and claims made or submitted by Defendant and its agents and employees paid and continue to pay Defendant for claims that would not be paid if the truth were known.

247. By reason of the Defendant's false records, statements, claims, and omissions, the United States has been damaged in the amount of many millions of dollars in Medicare reimbursement costs.

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## IX. PRAYER FOR RELIEF

WHEREFORE, Relators pray for judgment against Defendant as follows:

A. That Defendant ceases and desists from violating 31 U.S.C. § 3729 *et seq.*;

B. That the Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained as a result of Defendant's actions, as well as a civil penalty against Defendant of $11,000 for each violation of 31 U.S.C. § 3729;

C. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

D. That Relators be awarded all costs and expenses of this action, including attorneys' fees; and

E. That the United States and Relators receive all such other relief as the Court deems just and proper.

## X. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relators hereby demand a trial by jury.

Dated: October 14, 2006

Respectfully submitted by his attorneys,

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